SEAFOOD INSPECTION SYSTEM

HEARING

BEFORE THE

SUBCOMMITTEE ON FISHERIES AND WILDLIFE
CONSERVATION AND THE ENVIRONMENT

OF THE

COMMITTEE ON
MERCHANT MARINE AND FISHERIES
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

ON

H.R. 1387

A BILL TO PROVIDE FOR THE INSPECTION OF ALL COMMERCIAL SEAFOOD DESTINED FOR HUMAN CONSUMPTION IN THE UNITED STATES

AND

H.R. 2511

A BILL TO DIRECT THE PRESIDENT TO DEVELOP A COMPREHENSIVE SAFETY PROGRAM TO ENSURE THE QUALITY AND WHOLESOMENESS OF ALL FISH PRODUCTS INTENDED FOR HUMAN CONSUMPTION IN THE UNITED STATES

JUNE 7, 1989

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CONTENTS

Page

Hearing held June 7, 1989 1

Text of H.R. 1387 38

Text of H.R. 2511 40

Statement of:

- Brennan, James, assistant administrator for fisheries, National Oceanic and Atmospheric Administration 10
- Dyson, Hon. Roy, a U.S. Representative from Maryland 3
- Haas, Ellen, executive director, Public Voice for Food and Health Policy 4
  - Prepared statement 48
- Miller, Hon. John R., a U.S. Representative from Washington 2
- Pelosi, Hon. Nancy, a U.S. Representative from California 37
- Smith, Jo Ann, assistant secretary for marketing and inspection services, Department of Agriculture 16
  - Prepared statement 97
- Studds, Hon. Gerry E., a U.S. Representative from Massachusetts, and Chairman, Subcommittee on Fisheries and Wildlife Conservation and the Environment 1
- Weddig, Lee, executive vice president, National Fisheries Institute 7
  - Prepared statement 77
- Young, Dr. Frank E., commissioner of food and drugs, Food and Drug Administration 13
- Young, Hon. Don, a U.S. Representative from Alaska 2

Additional material supplied:

- Young, Dr. Frank E. (Food and Drug Administration):
  - Letter of 19 May 1989, along with copy of draft risk assessment, to Dr. Walter Dowdle, Centers for Disease Control 104
  - Revised risk assessment based on CDC comments 118
  - Inspection Methods for Fishery Products (Graph) 130
  - Copies of Memorandum of Understanding with foreign countries regarding shellfish and MOU's with other agencies regarding research programs for fishery products 132
- Dowdle, Dr. Walter R., (Centers for Disease Control): Letter of 31 May 1989, to Dr. Frank E. Young 116

Communications submitted:

- Press, Frank (National Research Council): Letter of 31 May 1989, to Hon. Gerry E. Studds 101

H.R. 2511 AND H.R. 1387, LEGISLATION TO ESTABLISH A MANDATORY SEAFOOD INSPECTION SYSTEM

WEDNESDAY, JUNE 7, 1989

U.S. HOUSE OF REPRESENTATIVES, COMMITTEE ON MERCHANT MARINE AND FISHERIES, SUBCOMMITTEE ON FISHERIES AND WILDLIFE CONSERVATION AND THE ENVIRONMENT,
Washington, DC.

The Subcommittee met pursuant to call at 10:15 a.m. in Room 1334, Longworth House Office Building, Hon. Gerry E. Studds, (chairman of the subcommittee) presiding.

Members present: Representatives Studds, Carper, Tallon, Ortiz, Pallone, Young, Schneider and Saiki.

Staff present: Jeffrey Pike, Susan Sponaugle, Lisa Murray, Joyce Sacco, Rodney H. Moore, Jr., Suzanne Waldron, George Pence, and Bill Woodward.

STATEMENT OF HON. GERRY E. STUDDS, A U.S. REPRESENTATIVE FROM MASSACHUSETTS, AND CHAIRMAN, SUBCOMMITTEE ON FISHERIES AND WILDLIFE CONSERVATION AND THE ENVIRONMENT

Mr. STUDDS. The Subcommittee meets this morning to conduct its first hearing on legislation to establish a mandatory seafood inspection system. That legislation includes a bill that I introduced two weeks ago, along with our Ranking Minority Member, Mr. Young, and also a bill introduced by Representative Byron Dorgan of North Dakota.

We will discuss the specifics of this legislation today, but we will also take a broader look at the question of seafood safety.

Does seafood, in fact, pose a significant public health risk to the American people? If so, can a mandatory inspection system reduce or eliminate that risk? How should such an inspection system be designed? Which Federal agency is best qualified to undertake the inspection of fishery products? And last, but not least, who should pay?

I think I speak for the entire Subcommittee when I say that these questions are, in our minds, not rhetorical, but real. Data on seafood-related illnesses are not adequate. As a result, it is not easy to distinguish fears from facts; or to separate matters of public perception from issues of public health. Thus, although our Subcommittee is prepared to take whatever action is necessary, we will not act until all those with necessary information have a chance to be heard.

For my part, I believe that even one avoidable death from seafood contamination or poisoning is too many. I believe that an inspection system must be designed with the special nature of the fishing industry in mind. I believe that we should build on, not ignore, existing state and Federal seafood safety programs. And I believe that, whatever financing system we use, that system should be the same for all producers of inspected food, whether that food is piscine, bovine or be-feathered in its natural state.

The witnesses we will hear from this morning represent those who produce fish, those who eat it, and those who now or who may in the future inspect it. I hope, and expect, they will provide a good starting point for the Subcommittee's consideration of this difficult and controversial issue.

Mr. STUDDS. The gentleman from Alaska.

Mr. YOUNG. I have a written statement I will submit for the record.

[The statement of Mr. Young follows:]

STATEMENT OF HON. DON. YOUNG, A U.S. REPRESENTATIVE FROM ALASKA

Mr. Chairman, I joint you in welcoming the witnesses who will appear today and look forward to hearing what they have to say on the complex issue of seafood inspection.

I want to emphasize your statement that this hearing is a starting point. The bill we have introduced is not perfect, and I know there will be a number of changes as we go through the hearing and markup process. Therefore, I think we need to listen closely to testimony on the bill, and on the general subject of seafood safety.

I also want to point out that this is not a new issue, and in fact it has already been addressed by a number of states, including my State of Alaska. As we develop our ideas, I hope we look closely at what has already been done, on the state and Federal levels, so we don't wind up inventing something that already exists.

Finally, a note of caution, we must make sure that, when we are trying to promote safe seafood, we don't accidentally—or on purpose—promote one type of harvesting or processing over another. We should be concerned about safe food products, not about how they are caught. I know that is not your intent, Mr. Chairman, and I hope we can make sure the witnesses understand that as well.

Again, I look forward to hearing what will be said today and in the future, so we can decide how to address this complex issue.

Thank you.

Mr. YOUNG. I want to point out this is not a new issue. In fact, it has been addressed by a number of states including the State of Alaska.

I don't think we need to reinvent the wheel or whatever we must do to promote this. I know we are all saying the same thing. I hope we will do the correct job without putting into contention any one type of fish harvested. I am reluctant to get into something that could possibly cause problems between one type of fish, one species of fish, one method of catching, one method of processing.

Sometimes we cause greater problems than already exist. We will have the witnesses and I welcome this today and welcome their presentation. Thank you very much.

Mr. STUDDS. We also have statements from Mr. Miller and Mr. Dyson to be included in the record.

[The statements follow:]

STATEMENT OF HON. JOHN R. MILLER, A U.S. REPRESENTATIVE FROM WASHINGTON

Mr. Chairman, thank you for holding today's hearing on the need for Federal seafood inspection. I welcome the opportunity to learn more about H.R. 2511, the bill you and Congressman Young have introduced. I also look forward to hearing more about Congressman Dorgan's bill, H.R. 1387.

I hope that today's hearing will address some of my concerns. First, let's make it clear that the seafood industry has an excellent record of policing itself and establishing wholesomeness and quality standards. The industry is not our enemy, nor is it opposed to any Federal program. Second, Mr. Chairman, let's give some thought to where we place this program. It should be located in an agency which does not look at inspection or at seafood as second cousins. their budgets are not there for constant shuffling. Third, the beef and poultry inspection programs are paid for by the taxpayer because they provide an important public service. If seafood inspection is needed for consumer protection, that program should receive similar Federal support.

Finally, Mr. Chairman, we need to think about the consumer. In this era of high cholesterol and heart attacks, people are eating more seafood because it is healthier. In designing any program, let us make sure that we do not scare the consumer away from a healthful source of protein. And, at the same time, if there are problems with wholesomeness, let's fix them.

Mr. Chairman, again, I want to thank you and Congressman Young for taking the lead on this important issue. Coming from the State whose fishermen harvest more edible fish than any other state, I can tell you that industry does not oppose a responsible program. Coming from a state known for its excellent seafood, I can tell you that consumers are becoming more knowledgeable. In fact, I too want to know more about the products I buy.

Mr. Chairman, we have an opportunity to develop a responsible program. I look forward to this hearing.

Thank you.

STATEMENT OF HON. ROY DYSON, A U.S. REPRESENTATIVE FROM MARYLAND

Mr. Chairman, I would like to welcome our distinguished panel. This is an important issue for my state and for any state with a thriving fishing industry.

I first became interested in the question of seafood quality while studying the environmental deterioration of the Chesapeake Bay. The Bay is this country's most productive estuary, but it has suffered from years of environmental neglect and abuse. Industrial, municipal, and agricultural pollutants have loaded the Bay's waters with heavy metals, nutrients, and organic compounds.

From the consumer's perspective, it is important to know that the seafood harvested from the Chesapeake Bay isn't tainted by these contaminants. Maryland state officials and the watermen of the Bay have done a good job of ensuring the safety of the Bay's harvests and of reassuring consumers.

But questions remain. Last summer hundreds of dead dolphins washed ashore along east coast beaches. We are still investigating the cause of their death. There appears to be no reason to fear that whatever killed the dolphins could effect the health of seafood consumers. But in the absence of a comprehensive national inspection program, consumers may remain concerned.

Any effective seafood inspection program will have to take a close look at the connection between overall water quality and the quality of the seafood harvested in those waters.

But there is another aspect of an inspection program. It will ensure that the handling and processing of seafood products are safe from unscrupulous business practices.

By ensuring that the food harvested from our waters is safe, and that it is processed and packaged reliably, both consumers and the seafood industry benefit.

Mr. Chairman, let me take this opportunity to commend your efforts to explore this issue. Your work will help us to determine whether in fact there is a genuine need for a Federal inspection program, how one would be financed and what Federal agency would be responsible for administering it.

I appreciate the chance to hear our witnesses this morning, and look forward to working with the Subcommittee on this matter in the future.

Mr. STUDDS. If there are no additional opening statements, we will go to our witnesses. We have asked you to appear as a panel. You have arranged yourselves that way. What I would like to do, as I gather the staff has told you, is impossible. That is to contain your oral statements to no more than five minutes.

I understand you all have statements of varying lengths, some of them considerable. It is a complex subject. All written statements will appear in the record in their entirety. For the purpose of being able to get to questions, we are going to ask you to be super human in your discipline and refrain or refine. Keep yourself to five minutes, if you can.

We will go in the order in which you appear, starting with Ms. Ellen Haas, Executive Director of Public Voice for Food and Health Policy. Welcome, Ms. Haas.

STATEMENT OF ELLEN HAAS, EXECUTIVE DIRECTOR, PUBLIC VOICE FOR FOOD AND HEALTH POLICY

Ms. HAAS. Thank you very much, Mr. Chairman.

I appreciate very much being here today and representing, as you said, the eaters of fish and seafood. I am pleased to be here to discuss the health risks that consumers face from eating contaminated, uninspected fish, and the inadequacy of current Federal and state inspection programs that leave consumers too often vulnerable to acute illness, sometimes death, and the long-term risk of cancer.

Since 1983 when Public Voice was first formed, we have been documenting the problems that consumers face. With our publication of a market basket of food hazards, we have consistently called for a mandatory fish inspection program. It goes back more than 20 years when consumers worked to see such a program unsuccessfully, so we applaud the chairman's concern and the Committee's concern today for convening this hearing, and also, Mr. Studds, for your introduction of H.R. 2511, which will be the basis of discussion as Congress moves ahead in this very critical area for consumers.

Americans have been consuming more and more fish. That is not really very surprising. It is a low fat, high protein alternative, but that healthful promise that exists for consumers too often turns into a hazard because of our problems because seafood is the only flesh food not subject to a comprehensive mandatory fish inspection program. And last year as public concern about the safety and wholesomeness of fish has increased, then the marketplace began showing that concern.

For the first time in eight years consumption went down by 2 percent. There are unique characteristics of fish that increase its potential for acute illnesses and disease, particularly from bacteria and parasites. I would like to name just a few of them. To begin with, fish, as you know, is harvested from an uncontrolled environment, which may be polluted with sewage, industrial chemicals, and pesticides, and it is going to be a long time, as we know, before those waters are clean.

Certain types of seafood like shell fish concentrate contaminants in their tissues. Also, even when refrigerated, fish usually deteriorate quickly and also finally, fish is very frequently eaten raw, which presents particular problems for consumers.

A summary of the Centers for Disease Control data shows that the total number of reported food-borne illness outbreaks traced to fish actually exceeded the total reported outbreaks traced to the combined number of beef, poultry, and pork.

In data from 1982 to 1986, seafood accounted for 56 percent of the total outbreaks when they were traced. That is more than beef and poultry and pork, which each represented only 12 percent. What is particularly significant about this fact is even though consumption of fish is increasing, consumption of fish is much lower than either beef or poultry.

We eat significantly more of the others. For example, we eat four times as much beef and three times as much poultry as we do seafood. In addition, we have, in our written testimony, done an analysis of combining this data with USDA food consumption data, and we found that the risk of food poisoning outbreaks from eating seafood is actually 10.4 times greater from seafood than from beef and 6.9 times greater than for poultry.

But acute illnesses are not the only problem. The long-term illness problems are less significant in those that come from the pesticides and other chemical contaminants that might be in our waterways because of industrial and municipal dumping as well as agriculture run-off.

Of all the domestic food samples collected and analyzed by FDA from 1979 to 1985, fish had the highest percentage of illegal residues, 5.2 percent. That is even higher than when you compare it to the market basket average, which was 2.9 percent. Unfortunately for the public today's inspection system falls far short of dealing with these health problems for consumers.

It is an inadequate patchwork, often voluntary, of Federal and state programs with weak standards and even weaker budgets. The National Marine Fisheries Service, which we will be hearing more about on this panel, is a voluntary program paid for by corporate users, and it covers only 11 percent of the seafood that is consumed.

What's more, its primarily marketing tool for the industry and a promotion tool for the industry and a promotion tool rather than a public health program. The Food and Drug Administration, which has authority to inspect seafood and interstate commerce has several programs under its authorities, but in 1987 FDA inspected only 789 plants that process fish and seafood.

That is just one quarter of the total of fish seafood processing plants in the country. Also, the monitoring of chemical and pesticide contaminants is woefully inadequate. While there are hundreds of toxins that can be present in the waters, FDA only has a tolerance for one, PCB's and only 13 action levels.

One example of a toxin that is in the water is dioxin, and there is no tolerance for that. Not only that, but the testing of chemical contaminants is woefully scanty. In 1987 FDA only analyzed 996 domestic and 628 imported seafood samples, though we consumed three billion pounds. Finally, the FDA has responsibility for the seafood—the Shellfish Sanitation Program, which is a voluntary program of states.

Again, we have a program that is far too inadequate for the kinds of risk that consumers face. In 1988, according to FDA's own report, 54 percent of the shellfish harvest came from nine states where those programs had major public health significant deficiencies.

GAO in its report in 1984 said that that program, because of its voluntary nature, never had the kind of authority to make a difference in protecting the public health because FDA's only sanction is to withdraw enforcement of a state program, but it is never done it. What can we do about these problems?

What can we do about solving this problem for consumers who face those kinds of public health risks? I think that there is growing consensus, both at this table and in Congress, that mandatory Federal seafood inspections is needed, and it is needed now.

We applaud your effort in introducing the bill that you have. It includes many of the elements that Public Voice has recommended in testimony and in its reports. In particular we are pleased to see that the following points are included in your bill—the Federal standards for sanitary conditions and good manufacturing practices for fishing vessels, the requirements that there be good manufacturing practices and authorization of spot checks of processing facilities, the establishment of microbiological and chemical contaminant standards, the improved standards for imports, and the establishment of a trace back and recording system are all examples of the kinds of components that are essential in any kind of mandatory fish inspection program.

We also applaud the fact that you are basing the bill which we feel that such a program to be operated correctly needs to come from appropriated funds. We have estimated that it would cost between 75 and 100 million dollars.

It is particularly important when we are talking about a public health program and not a marketing program that this be appropriated funds rather than industry user fees, which would really compromise the kind of objectivity that inspectors need.

Finally, we believe that the Department of Agriculture should be the lead agency with the monitoring of chemical contaminants retained by the Food and Drug Administration. I would be happy to answer further questions on that, but we believe that with the infrastructure that exists at the Department of Agriculture already with meat and poultry inspection, the resources and also the large research establishment that is there at USDA and the close links with the nutrition that it would be the appropriate agency.

In conclusion, Mr. Chairman, on behalf of Public Voice and the 35 public health environmental consumer and senior citizen organizations, we look forward to working with you in this critical area and closing a gap in consumer protection that should no longer exist. Thank you.

[The statement of Ms. Haas can be found at end of hearing.]

Mr. STUDDS. Thank you very much, Ms. Haas.

Let me say one thing I should have said at the beginning. If there are people who are unable to find a seat, and clearly there are, especially those of you who need to write, we will take a moment if you want. You are welcome to come in and fill in this first dias here, if you can get by the other media.

We assure you not to worry. You will not be accused of being Members of Congress. OK.

We will go now to our next panelists, Mr. Lee Weddig of the National Fisheries Institute.

Mr. Weddig, welcome.

STATEMENT OF LEE WEDDIG, EXECUTIVE VICE PRESIDENT, NATIONAL FISHERIES INSTITUTE

Mr. Weddig. Thank you, Mr. Chairman.

We appreciate your introducing the bill, along with Congressman Young, and holding this hearing. The issue has been with us for a very long time, and it is appropriate to mention that the first testimony I ever delivered on behalf of the fish industry occurred 22 years ago. It was on fish inspection, and we think that 22 years is rather long to let an issue dangle.

We would really like to see it brought to a head during this session of Congress. The Institute, speaking for the seafood industry, believes that there is a need for an inspection program. There are some real public health problems, even though we don't believe they are as extensive as perhaps has been depicted.

There are many perceived problems which have to be brought to rest, and there are many changes occurring in the fish and seafood industry that hold the potential for problems unless we address them before these problems could develop; and finally there are some economic and industry problems that have to do with economic cheating, that have to be corrected through better enforcement.

I think the value of the seafood industry to the public and to the economy is well-known to the Members of this Subcommittee, but I would like to make a few points that I think might illustrate it and show why it is important to come to grips with this issue.

A recent study that we conducted indicated that the total economic impact of the seafood industry; and I am talking about direct impacts, indirect impacts, and induced impacts; comes to $80 billion a year; and more than one million jobs center in the seafood industry and the related economic impacts.

Now, that is a very large portion of our food economy and important to many coastal areas and states, as you know. Despite the growth that has taken place in the industry and the size that it is in now and the importance that presents economically as well as a provider of good wholesome food, it is a precarious industry, and I think the events in Alaska illustrate that.

The precariousness of bringing foods in from the sea where a single accident can jeopardize a part of the industry, where more immediately a heavy rain storm here in the Chesapeake can close down an oyster bed or oyster beds, a hurricane can wipe out an industry, destroy a habitat. We are a precarious industry, and because of that when anything comes up that can shake consumer confidence, it does have an immediate impact.

I would like to illustrate that. Miss Haas mentioned how seafood consumption has been growing, and that it has. Over the last five years, from 1982 onward, per capita consumption increased about 25 percent. Last year it took a dip. The dip occurred entirely in fresh and frozen fin fish which have been the fastest growing part of the industry.

The reasons for that dip, which amounted to as much as 10 percent in the categories that were affected, can be tracked to three things. The one element was price, pure and simple. Prices in certain commodities had risen very rapidly in 1984 and 1987. They peaked at the end of 1987, causing some buyer resistance in certain large commodities.

Point Number 2, the value of the yen and other European currencies made our products a bargain overseas. As a result, we shipped more than 200 million additional pounds of seafood from our producers overseas. This took supply away from the domestic market, again causing reduction in per capita consumption.

The third element, however, had to do with consumer confidence. The incessant press and publicity that took place, particularly in the East Coast during the summer of 1988 did have an effect on the purchase of seafood in the Northeast and the mid Atlantic states.

I would like to illustrate for the benefit of the Chairman just what a shake-up in consumer confidence can mean to his constituents. The price paid at the boat level for cod fish from the Atlantic in 1987 averaged 75 cents a pound. In 1988 it averaged 56 cents a pound despite the fact that there were fewer fresh cod imports being brought into the country.

The price on yellow tail dropped on an average from $1.25 to $1.18 despite the fact that the catch was reduced. The price on other flounders dropped from $1.11 to $1.05, despite the fact that the catch was reduced. Atlantic pollock dropped from 39 cents to 33 cents, despite the fact that the catch was reduced. Now what does this mean?

For a typical New Bedford dragger that might bring in 500,000 pounds of fish in the course of the year, half of which is cod, half the other flounders and yellow tail, the gross income for that boat in 1987 would have been $477,000. In 1988 the gross would have been $416,000, despite the fact that the men would have been doing the same amount of work and bringing in the same catch.

Translated farther, down to the deck hand on the boat, that shake-up in consumer confidence meant his income dropped from $35,775 to $31,220. I would hope that this would illustrate the need to make sure that consumer confidence in seafood products is maintained because it has a very real effect on some very real people.

We believe that seafood is a good wholesome food, and the real problems are very small in relationship to the total and that they are isolated, but we do know that there are many perceived problems.

One of the reasons that the problems are perceived, there is a perception of problems, is because there is a lack of a comprehensive regulatory system which would provide the authorities the data and the information that they can speak out and assure the public that despite the fact that they may see pollution, that there may be beach wash-ups, that there might be medical waste and all of this other stuff which has no bearing on the seafood safety, there is nobody who speaks out and says that it doesn't have a bearing on the safety. That is what we must have out of the Administration, someone who has the confidence in his program who can stand up and say, the product is safe, which it is.

There are other changes taking place in the industry. We are bringing in new species from other parts of the world. Processing operations are emerging in other parts of the world, and these are far removed from our inspecting agencies.

We have processing taking place in Taiwan and Thailand, in the Philippines. We need to have a system that makes sure that that processing, because that food is ready to eat when it gets here, that that processing is being conducted in completely sanitary and good manufacturing practice procedures.

Aqua-culture is coming on as a major source. It now approximates 10 percent of our supply, and it is going to grow. Aqua-culture opens up other areas of concern. Medication and the other uses of therapeutics that are involved with husbandry will take place in the husbandry of farm fish as well. We have to have that under control.

There is new processing technology. There is growth in ready-to-eat processed seafood, which means more concern has to be made for the sanitation and procedures in the plants. We are processing at sea, and those vessels are not within easy reach of inspectors.

New bacteria and virus are being recognized, and they bring on the need for new procedures and good manufacturing practices. Finally, we do have the continuing environmental concerns which are not going to go away and which have to be addressed by a comprehensive day in, day out monitoring of the safety of the product.

NFI has been working on this for quite sometime. We got into it in 1982 with a quality committee because we were concerned with economic deceptions being perpetrated in parts of our industry, and we wanted to stop them. We thought education might do it.

We went to the trade. We went to the retailers. We went to the food service industry. We told them to watch out, to look out for deceptions that could be placed on them by unscrupulous operators. After two years of education we felt that was not enough, that regulation was the answer. Our group said let's go after inspection. Let's go after a mandatory program, and that is when we asked Congress to initiate the study that is being undertaken by the National Marine Fisheries Service.

That work has been going on for two years. It is based on the HACCP Program, which I am sure will be described in detail by others. We support a mandatory seafood inspection program that would be built on the HACCP system, one that is designed specifically for the seafood industry, one that places the same controls on imports as domestic product, one that provides additional monitoring toxic substances and environmental concerns, and one that places greater enforcement, I should say, on economic issues.

Thank you very much, Mr. Chairman, and Congressman Young for introducing the bill which will get us started on this process. We will be happy to work with you over the coming months to see that it is enacted into law. Thank you, sir.

[The statement of Mr. Weddig can be found at end of hearing.]

Mr. STUDDS. Thank you very much, Mr. Weddig.

Next, Mr. James Brennan of the National Oceanic and Atmospheric Administration. Mr. Brennan, welcome back.

STATEMENT OF JAMES BRENNAN, ASSISTANT ADMINISTRATOR FOR FISHERIES, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

Mr. **Brennan**. Thank you, Mr. Chairman, and Members of the Subcommittee. It is a pleasure to have the opportunity today to appear before you on behalf of NOAA and the Department of Commerce to address seafood inspection, specifically H.R. 2511, the Consumer Seafood Safety Act of 1989.

Mr. Chairman, I know my position on this panel, I am directly in the middle between my colleagues from the Department of Agriculture and FDA and my friends from industry and the consumer representation. I hope, Mr. Chairman, that this is an indication that you believe that National Marine Fisheries Service, as always, takes a middle of the road, reasoned position on all issues of national importance relating to fisheries.

Mr. **Studds**. Yes, there appears a danger of overdoing that. I wouldn't want to be known as an ultra-moderate.

Mr. **Brennan**. The public interest and the industry interest implicated in H.R. 2511, in fact, is considerable. The Administration recognizes the importance of this issue and is attempting now to address it within the Administration. It does not at this time support enactment of any legislation which imposes new requirements for seafood inspection, because the issue is, in fact, currently under review.

The Administration has not yet developed a position on which agency should administer such an expanded program if the Congress chooses to establish one. In my testimony today, however, I will review one of the alternatives being considered within the Administration. First of all, to place the situation in perspective, I believe that the U.S. consumer is not, in fact, facing a major health problem.

Nevertheless, as has been pointed out, certain fisheries do require stricter regulation to prevent practices such as marketing of shell fish from harvested commercial and recreational,

And parenthetically, recreational fishermen are at great risk in harvesting from polluted waters.

And to address the problem of scombrotoxin.

These three problems, shellfish, scombrotoxin, ciguatoxin, account for almost 90 percent of the public health outbreaks with confirmed etiologies as reported to the Center For Disease Control for the period of 1982 to 1986.

They require obviously that the publications, both Federal and state, concerned with public health and with fisheries management, address these problems. At sea regulatory efforts are clearly necessary, because unwholesome products cannot be fixed in the processing plant when unwholesome product is delivered to the processing plant.

I think it would be useful to review some of the more successful programs that exist in other countries with respect to seafood inspection. A review of the success of these major food producing countries in capturing and maintaining significant shares of the world market, including their own, reveals several similarities in the manner in which the safety and quality of their seafood are addressed. They have in comment a commitment, clear leadership, and effective organizations of authorities, and responsibilities to assure safety.

Quality and proper handling is a matter of governmental policy, whether for domestic consumption or for export. Again, Mr. Chairman, the United States is the leading exporter of fishery products. We have much at stake in the international market in order that that status continue.

Product control systems to address safety, quality, and proper labeling from the point of harvest to the point of sale.

Government and industry cooperation to establish technical products and processing standards that are used to achieve industry-wide uniformity.

Mandatory controls and inspection requirements on domestic harvesting, processing, and distribution facilities and products to address sanitation and wholesomeness problems.

Mandatory standards applied equally to the facilities and products of importing countries to maintain uniform consumer protection and to ensure that domestic markets are not inundated with questionable product that competes with domestic product unfairly.

Again, Mr. Chairman, this is particularly important for the United States. We import approximately two-thirds of the fish that finds its way to the tables of our consumers. If the United States is to maintain its position as a leading producer of and a market for fish and seafood products, our products must meet similar levels of product assurance quality and labeling.

Fish and shellfish in the United States are handled and processed by many entrepreneurs, some very small operations, whose equipment and awareness of good storage and processing techniques vary from rudimentary to sophisticated. The difficulty of providing plant inspection for the hundreds of independent fish processing plants is complicated by the fact that there are over 125,000 vessels which harvest fish that go to the processors. The production seasons vary, these vessels are very mobile, they operate according to what is running, and what season is on, and they are here today, gone tomorrow, and back again the next day.

Compounding this is the fact that 65 percent of the seafood consumed in the United States, as I have said, is imported from over 120 countries. Some of these countries have varying degrees of seafood inspection competence.

Finally, and I think this is also a very important point to bear in mind, much of the seafood that is harvested is sold fresh in intrastate markets, necessitating a strong and continuing involvement of the states concerned with the problem.

There are a variety of issues that we believe should be addressed in deciding whether to implement a new seafood program, including potential changes in seafood inspection philosophy and program design, the adequacy of regulatory and enforcement authorities in appropriate Federal and state roles, and establishment perhaps of an industry levy to pay for the program costs.

The Administration will consider a seafood inspection system based on probably prevention backed by a strong enforcement similar to the approach of leading seafood producing countries, such as Canada.

The Administration will consider changes in system design, including developing and implementing a seafood inspection program based on the hazard analysis critical control points concept, which was mentioned earlier by Mr. Weddig. These would be tailored to the need of the individual fisheries that address the issue of plant and vessel sanitation product safety and economic fraud, prohibiting or restricting to fisheries management plants are similar efforts harvesting fish from areas to prevent processing and marketing of unsafe fishery products, developing and maintaining minimum mandatory sanitation standards for harvesting, processing, transporting and storage of fishery products. Developing or amending production related fishery product standards, consistent with international standards pertaining to quality, minimum quality, packaging and labeling.

The Administration is reviewing the advisability of creating a mandatory plant and vessel registration and certification system, granting access to records pertinent to HACCP principles, granting production inspection facilities for domestic products to inspectors, and imposing stricter civil penalties for specified violations of prohibited acts.

Furthermore, we are considering granting authority to establish and monitor technical arrangements with appropriate agencies for foreign governments for mutual acceptance of inspection systems or results.

The Administration, with respect to Federal/state responsibilities, will review the continuing joint responsibility of NOAA and the Food and Drug Administration for seafood inspection and enforcement with a view toward continuing and expanding that awareness, and maintaining current responsibility within FDA for health standards and to oversee NOAA fisheries and inspection and enforcement, with particular emphasis on public health issues.

We are also conducting within the states approved programs equivalent to those in the Food and Drug Administration and NOAA. The Administration believes that funding for increased seafood inspection should be paid for by the industry for user fees. The specification of an industry user fee depends on the outcome of the review of a need for the additional activities.

Mr. Chairman, your bill addresses many of the issues we believe are important in the area of seafood inspection. As stated, the Administration does not support enactment of any new seafood inspection legislation at this time, but we look forward to working with the Congress and to address the important national interest in the safety and quality of seafood.

Thank you very much, Mr. Chairman.

Mr. STUDDS. Thank you, Mr. Brennan.

Mr. STUDDS. Next, Dr. Frank Young, Commissioner of the Food and Drug Administration.

Welcome, sir.

STATEMENT OF DR. FRANK E. YOUNG, COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION

Dr. YOUNG. Thank you very much, Mr. Studds. It is a great pleasure to appear before you and to present to you and your Committee the important issues that are facing you today.

I particularly am pleased to have the opportunity to discuss primarily the health focus, because I believe that your first question to us was one of the most important issues that needed to be focused on today.

Mr. Brennan has aptly described, and I concur, with the Administration position as it is today. I will not take, therefore, time to detail, as I have in our testimony, the extensive interaction both in the programs and the research that we have between NOAA and ourselves, nor will I go into the mandatory program that exists in the Food and Drug Administration at this time.

What I would like to do instead is to use my limited time to focus on what I think have been some misunderstandings in regards to the true issues, with regard to the health concerns. To provide this for you, we submitted a risk analysis to the Centers for Disease Control, and I shall submit this for the record, and have received back an answer from them which validates the information that I will be presenting today. Because Ms. Haas has started with the CDC outbreak data, I will take that as my fundamental point of departure. And then I will move into the other issues, and I will illustrate these on graphics for you.

[Copies of the Food and Drug Administration/Centers for Disease Control correspondence regarding risk assessments for seafood as compared to other sources of muscle protein can be found at end of hearing.]

The first focus is probably the most important, and that is to distinguish very clearly between what is called an outbreak, the analysis of individual cases in that outbreak, and the analysis of sporadic cases.

Whether we report as physicians to the CDC or to our state health departments—and I served as a Health Department Microbiologist for a number of years—we report the total number of cases. They will fall into two categories, sporadic and outbreak.

In this particular chart it will show that by outbreaks, all foods other than seafood constitute 80 percent of the totals food borne illnesses.

Mr. CARPER. Mr. Chairman, would it be possible for your aide to raise the chart so we can all see it?

Dr. YOUNG. Why don't you put it on top of the other chart? That would bring it up even higher.

Is that okay?

Mr. CARPER. That is perfect. Thank you.

Dr. YOUNG. If you now correct these by individual cases within those outbreaks, which is really what you pointed to—people being sick, not outbreaks being sick—you will notice that 95 percent, not 80 percent of those come from other foods, and only five percent, roughly equally divided between fin fish and shellfish.

Starting now—if you could lift the next one up—starting now at the point of Ms. Haas' data—and this exactly confirms where she was--you can see that there is a tenfold difference in the number of outbreaks between beef and fish and shellfish, but that is not the issue. The issue is not outbreaks. The issue is number of people ill.

Now, in order to handle those differences, now you have to look at the size of outbreaks—and please interrupt me at any time if I am going too fast or not covering the points, or you cannot see the charts. If you look at the size of outbreak, that is the number of people that get ill from each particular outbreak, you will note that for foods other than seafood, the average is 53. For fin fish, the average is seven people per outbreak. For shellfish, the average is 22, and from fin fish plus shellfish—that is all seafoods—it is 11.

Now, I must point out very clearly, as we all know, that there is a dramatic difference between the habitat of shellfish and the habitat of free swimming fin fish. The former are fixed in the particular environment and the strategy that has been done both by the states and the Federal Government is to focus on the quality of the waters that those shellfish reside in, because they do concentrate microbes and they do concentrate viruses.

In fact, I am surprised as I reviewed this information, that we did not see more illnesses associated with shellfish, because, remember, shellfish are often eaten raw and the entire animal is consumed, including the viscera of the animal. If one were to eat raw beef and poultry, we would see and expect to see even higher figures than with raw shellfish. I think, in a sense, this relates to the ability of those programs to control it.

Now, if you normalize these—if I could have the next one, please—to the number of cases per billion pounds consumed, and now look at the number of cases in each of these outbreaks, you will note that beef still remains the lowest, then poultry, and shellfish plus fin fish at 171 cases per billion pounds in reported outbreaks.

None of this includes the sporadic cases.

May I have the next one, please.

Now, if one looks at the vast majority, over 90 percent of fish consumed, which is fin fish, you will note that, as we remove raw shellfish—and I emphasize raw, not cooked shellfish—from this, you will note that poultry, not fin fish, is the primary product that is associated with disease.

Now, I do not want to leave a misimpression that eating flesh of animals is harmful to health, because good processing with cooking, with the exception of the two toxins that were clearly mentioned by Mr. Brennan, inactivates, kills most of the viruses and bacteria. In fact, some of the greater problems associated with poultry are consumer problems with inadequate cooking or mixing cooked and partially cooked food. But I think that shows essentially a level playing field.

Now, if we go further and add the sporadic cases, one comes to, I think, some of the more interesting figures. Because in this case, as CDC has verified, we are now looking at chicken versus seafoods and comparing pound per pound consumption, taking cases in outbreaks, plus cases in sporadic nature that are not reported.

For example, if you had a problem with a fish meal that you ate, that would be a sporadic case. If you had a party at your home and served fish to 22 individuals, and 15 of them became ill, that would be an outbreak. But you would have 15 individuals there and you have to add up individuals rather than outbreaks.

If you now take sporadic plus outbreaks and look at these, you find that chicken is seven to 11 times more likely to make you ill than seafood, chicken is two to eight times more likely to result in death versus seafood.

If you compare fish excluding the raw or partially cooked molluscan shellfish per pound; chicken is 150 to 200 times more likely to make you ill than fish, excluding shellfish. Now, I believe that those kinds of data which I am submitting for the record should be analyzed. We want to be sure that we are absolutely correct, which is why we submitted these to CDC for analysis. But I think, Mr. Chairman, it focuses on the issue that you requested that I focus on—what is the public health information at this time, to the best of our knowledge?

I have said, to Ms. Haas, over a number of interviews we have had together, that I, too, believe that we need to increase the inspection within the seafood industry.

I believe that is important and we, together with NOAA and Agriculture, have looked at microbial contamination in a wide variety of products and no one in the Food and Drug Administration looking at HACCP principles in dealing with the critical analysis of hazards so that we can focus on these particular issues.

The final point that I would like to raise is just a slight correction, that is, though we have not decertified programs we have delisted a number of them and the threat of delisting and decertification is no small threat to the shell fish industry and I believe the New York Times picked that up in one of our great States in the Northeast a short time ago.

I was asked to characterize our program in a one liner. I would say that our program is a comprehensive program, a good program, but an anemic program. It lacks iron. The iron in this case is the greenbacks to get the job done, and we would support the approach of NOAA with the Administration, which is the consideration of the program endorsed by user fees, recognizing that we have a budget deficit and disability in our economy today. We are out of balance and we need to leave to our grandchildren some hope of progress in the future without a large amount of red ink. Therefore, I proposed and support the user fee concept.

In conclusion, I believe that—if I could have the next slide, please—that it is very important to look at terminology. Mandatory is different than voluntary, but continuous is different than mandatory. We have a mandatory program, but it is not continuous.

Let me show you on the graph what inspection programs can show. You have the inspection data slide. It is important to know what can be seen by different types of inspections. I will submit this for the record.

[Graph depicting contaminants and what types of inspections must be conduced to identify them can be found at end of hearing.]

Bacteria can be either no hazard or fatal. You cannot see them on the visual or organaleptic, but they can be seen on the laboratory analysis. Viral diseases cannot be seen visually, organoleptically, i.e., smell, but you can see them in laboratory analysis.

Industry chemicals you cannot see visually. You need laboratory analysis. The same is true with pesticide. You can see decomposition, filth. Natural toxins cannot be determined. Parasites, if they are large enough, are visible; otherwise you need laboratory work.

In summary, we believe that a vary careful multidisciplined, integrated program as described in the testimony is the appropriate way to go. And I thank you and would be ready to answer any questions.

Mr. STUDDS. That was an extraordinary statistical job you have done there. Thank you.

Are you available for biblical exegesis?

Dr. YOUNG. I am. I would call your attention to probably Romans 11:23, which said all have sinned and come short of the glory of God. That means you have to watch everybody.

Mr. STUDDS. I knew it.

Ms. Jo Ann Smith, speaking for the Department of Agriculture.

STATEMENT OF JO ANN SMITH, ASSISTANT SECRETARY FOR MARKETING AND INSPECTION SERVICES, DEPARTMENT OF AGRICULTURE

Mrs. SMITH. Thank you, Mr. Chairman.

On behalf of the Department of Agriculture, I appreciate the opportunity to participate in this hearing today and I commend you on behalf of the Department for holding the hearings.

We are concerned at USDA about the issues as laid forth by your questionnaire to us. We remain open, objective. We have not reached decisions on all of the issues and we think that this hearing is certainly a way and a method in the right direction to make some obvious conclusions and determine steps that would need to be taken.

The Administration recognizes the importance of continuing the assurance that seafood products are safe and we would review how best to accomplish this.

Let me take the time to share with you our position as it relates to FSIS, Food Safety and Inspection Service, at the Department of Agriculture, who is the regulatory agency for meat and poultry products and is the public health arm of USDA. We think it is important for that to be on the record and reviewed in order to look at seafood inspection.

Over two decades ago, FSIS added mandatory poultry inspection to the ongoing meat inspection program. It would not be unlike the program that would have to be developed in order to address the issue you are looking at today. FSIS is well-suited for managing the seafood inspection program. The laws protect the consumer by ensuring they have safe, wholesome, unadulterated and properly labeled products.

This fiscal year the budget is $405 million. Almost $37 million of those dollars go to State grants that have up to one-half of matching funds in State inspection.

FSIS already has in place a supervisory and administrative infrastructure through five regional offices, 26 area offices, 189 inspection circuits, and 7,000 inspectors for approximately 6,900 meat and poultry slaughtering and processing plants. These people are very professional, trained inspection personnel. FSIS would be dedicated to, and of course in our own operation today has, a continuing education and training program for inspection staff which is conducted at our newly opened and dedicated center at Texas A&M University.

There seems to be a universal consensus that the HACCP system is one that should be considered for further development in the seafood inspection program. We realize that there are critical points where it needs to be inspected and certainly control monitoring is ongoing. Our scientific orientation includes a work force of chemists, microbiologists and other scientific support staff.

In 1988, we performed 1.2 million analyses for chemical and microbial contamination, parasites, additives and species substitution. We have state-of-the-art laboratories located in Alameda, California, and St. Louis, Missouri, with a network of 315 accredited private laboratories.

We currently conduct currently a very thorough label approval program for all domestic and imported meat and poultry products. They are reviewed to prevent false and misleading statements. This label approval program develops a format for standard identification and composition.

We certainly need to recognize the large importation of seafood, and FSIS currently inspects meat and poultry from 30 countries and certifies exports to over 70 countries. We certainly would encourage a process similar to our meat and poultry review system for foreign countries inspection programs and their facilities. We currently maintain an established network of contacts with foreign inspection officials throughout the world.

We have a very strong and vigorous compliance program and this past year reviewed 56,000 cases with some 24 convictions from those.

You have heard today more than once that certainly for this 5 percent of foodborne illness that we are addressing, that the process of cooking and how it is handled is most important. We have an ongoing, continuing education program to talk to the consumer about how to handle meat and poultry. We operate a hot line for questions that come up on various issues concerning these products.

FSIS maintains an excellent relationship between Federal and State programs in inspection. We monitor 28 State inspection programs for products to be sold only within that State and those programs must be equal to Federal inspection. State plants under the Talmage-Aiken Act are Federally inspected plants.

Let me say that in the 1950s, we incorporated into an ongoing meat inspection system the poultry inspection system. There was much public debate and concern and concern by Congress not unlike what you are looking at today as we look at seafood inspection, and congressional action at that time, of course, modified a voluntary system to become a mandatory system to address the poultry inspection and as we look at it today, this is the analysis that we are reviewing.

Mr. Chairman, this concludes my oral comments, and I will be happy to answer questions as presented.

Mr. STUDDS. Thank you. I appreciate that.

Mr. Studds. Let me see if I can focus initially, or clarify, or elicit where we agree or disagree.

Mr. Brennan, both Ms. Haas and Mr. Weddig are explicit in their support for a mandatory seafood inspection system.

The Administration is, as I understand, thinking.

Mr. Brennan. Yes, Mr. Chairman, the Administration is, indeed, thinking.

Mr. Studds. Reference was made to grandchildren, are we anticipating a position prior to their adulthood?

Mr. Brennan. I think it is reasonable to expect a position this year.

Mr. Studds. This year?

Mr. Brennan. Yes.

Mr. Studds. Mrs. Smith, for the record, who pays for the inspections conducted by the Department of Agriculture of beef and pork and poultry?

Mrs. Smith. It is an appropriation from Congress into our budget.

Mr. Studds. Do you know roughly, how much, all taken together that would be, by an order of magnitude?

Mrs. Smith. This year it was $405 million for the inspection.

Mr. Studds. You know more than roughly, you know precisely?

Mrs. Smith. That is correct.

I came prepared on that one.

Mr. Studds. That is for all meat and poultry?

Mrs. Smith. Yes.

Mr. Studds. Does your department believe that seafood inspection should also be similarly financed?

Mrs. Smith. The options are still being considered and we are looking at them very carefully.

It has been, of course, a concern and as we have reviewed this time and again, it has come before the Congress we feel that you have to when it is a very broad-based consumer served issue such as meat and poultry, that the inspections should be borne by the Government.

If it is an identifiable segment that can be identified very clearly, that is something that could be for a share and not a total part of the consumer and/or for industry, then that should be paid for by that segment.

Let me add that today for the meat and poultry inspections, if the plants run overtime or holidays at their call, that service is paid for by the plant, not by the Government, because it is a request of additional time.

Mr. Studds. I am going to ask unanimous consent that you be permitted to review and extend—revise, not extend. It is not your fault.

I don't mean to be flippant or angry at you, but that was a yes or no question.

Mrs. Smith. We have not taken a position as I stated earlier.

Mr. Studds. Let me see if I can try it another way—does anyone on the panel disagree with this proposition, that however—assuming we go to some kind of an inspection program for seafood, that however it is paid for it is only fair that it be in the same manner as we pay for inspection of the meat and poultry?

Mrs. **Smith**. We would agree with that.

Mr. **Studds**. Dr. Young?

Dr. **Young**. I would not necessarily agree with that at all. I think that we have to clarify a couple of things.

First, we do, at this time, have a mandatory seafood inspection program at the Food and Drug Administration. It is not doing what any of us feel is appropriate because it is underfunded.

If we are going to increase seafood inspections, the Congress of the United States has to make a decision as to how it is going to deal with these budgets. I would give you a comparative figure.

The whole budget of the Food and Drug Administration, which stands to regulate 25 percent of the economy, is only slightly more than $100 million more than the USDA food inspection service on poultry and meat alone.

As we adjudicate these issues, we are going to have to see where revenues can come for discretionary programs and user fees is, I believe, a viable option.

Is it fair to charge one different than another? I don't know, but I think that the issue of fairness has to be looked at in the context of the need for revenue, so I would disagree in part.

Mr. **Brennan**. If I could add something , please bear in mind that 63 percent of the produce that we are talking about being inspected is, in fact, imported.

If we have an appropriation program that will mean that the American taxpayer will have to foot the bill for the competing products coming in from abroad so this idea of competition and level playing field, the analogy can't be drawn too far.

Mr. **Studds**. How do we handle beef and poultry or do we have such a thing?

Mr. **Brennan**. We have very little of it.

Mr. **Studds**. I could have sworn I have seen some beef from elsewhere.

Mrs. **Smith**. We have an agreement with those countries that in order to come in there is a law that says that they have a system in place, and this is monitored, that is equal to the inspection system within the United States .

Mr. **Studds**. Excuse me—monitored by whom?

Mrs. **Smith**. We, at USDA, make sure that those facilities are monitored and make calls on those plants to make sure that they are in place.

Mr. **Studds**. You, yourselves, do the monitoring?

Mrs. **Smith**. Yes, we monitor for them.

Mr. **Studds**. Who pays for that?

Mrs. **Smith**. It is paid for out of appropriations because we have those people in the foreign countries inspecting and monitoring those plants.

Because that product is coming in to the consumer in the United States and when Congress mandated the mandatory poultry and meat inspections, it was to protect the consumer with a wholesome product, whether it was domestic or foreign.

Mr. **Studds**. Presumably, that is precisely what we are talking about here?

Mrs. **Smith**. Yes.

Mr. **Brennan**. We are talking about a large difference relative to imported versus domestic products in the beef and fish industry.

Two other points, as Dr. Young has said, there is, in fact, in place a mandatory inspection program. That has been in place for some time.

We have heard Mr. Weddig say that that is not adequate in the industry's view and that fishermen are losing money because of the inadequacy of the inspection program if I heard him right.

It would seem to me that a large part of the benefit derived from an inspection program would be going to benefit the industry, than the user pay philosophy that seems to be entirely appropriate.

Mr. **Studds**. How is that different from the other industries?

Mr. **Brennan**. The other industries are not complaining at this time that the mandatory inspection system is insufficient to engender consumer confidence to the level that they would like.

Mr. **Studds**. If the record could reflect your expression, the seriousness with which we are supposed to take that observation.

Mr. **Brennan**. May I say one other thing with respect to collecting fees, fee for service.

I think Ms. Haas has implied that there arises a conflict of interest in it in the case where the Government is directing a user fee and that fee can ultimately pay the salary of the inspector.

I believe that our current fee for inspection basis does not bear out that there is any problem in that area.

Mr. **Studds**. My original question here was one of fairness, and the question I threw at you was does anyone disagree with the proposition that if we are going to have comprehensive mandatory public inspections of food in this country on the grounds of reassuring the people that they will have safe things to eat, is it not equitable and fair to treat all segments of the food-producing community in the same way, whether it is beef or poultry or fish?

Leaving aside for the moment what that way might be, whether it is the user fees or proposed funds, my question is can anyone justify singling out and treating differently any one major food-producing sector of the country?

Ms. Haas?

Ms. **Haas**. Not only can I not justify singling out seafood, which I would argue does not have a mandatory inspection program. We saw with the data that shellfish present probably the most serious problem.

We have a voluntary program at NSP which never has the FDA enforced with any kind of withdrawal of the rights for a state to have that program. That has resulted in the illnesses faced.

On the other hand, we have a very rigorous meat and poultry inspection program, and we see again when you look at the data that there is a consistency that meat and poultry have less incidence of food-borne illness for consumers.

And I see no reason today when we have such a healthful product and we have the National Academy of Sciences and the Surgeon General recommending that consumers eat more fish because it is lower in fat that we should be arguing really about whether or not we have this kind of program instead of talking about how we can do it.

Mr. STUDDS. In all fairness, you changed the subject a little bit there. You got into the disputed area and upset Dr. Young enormously.

Mr. Weddig.

Mr. WEDDIG. Thank you, Mr. Chairman. We believe that what is good for the goose is perhaps good for the fish, too, so if it is going to be taxpayer-supported over at the Department of Agriculture for our competitive products, we think it should be tax-supported here.

If that is going to be a for-fee basis, we are willing to look at for-fee.

A point I would like to make, following up on one of the conversations regarding the amount of imported product, is that the amount of imported beef, poultry and pork last year amounted to 2,670,000 pounds; seafood, 2,700,000 pounds.

So it is virtually the same.

Mr. STUDDS. As a percentage of the whole——

Mr. WEDDIG. It is a greater amount for seafood, but in terms of tonnage it is virtually the same. In terms of export, we exported over a billion pounds of product worth over $2 billion, which is far greater than the amount of exports of meat and poultry.

Mr. STUDDS. It is a very important subject and it is complex, and there are areas of disagreement and controversy within each of its complexities. That is why I was trying to focus on one thing at a time.

Mr. Young?

Dr. YOUNG. My point was in no way related to statistics. I think that the Congress and the Administration will have to come to grips with the fairness issue on one side and the amount of revenue on another.

I think that is a fundamental conflict.

Mr. STUDDS. Share the revenue fairly?

Dr. YOUNG. No, the desirability of increasing something when we don't have any more revenue to pay for the programs.

Mr. BRENNAN. The Administration's position is, in fact, that funding for any increased Federal seafood inspection activities should be paid for by the industries through user fees.

Dr. YOUNG. So much for fairness?

Mr. BRENNAN. Not necessarily, but your question implicates a debate about meat inspection. I would defer to Agriculture about that.

Mr. STUDDS. Any of you who speak for the Administration, your assignment is to tell us either later today or at a later time what their response to the fairness problem is and how you can justify providing public funds to assure the safety of the product of one segment of the food production of this country and asking another major segment to provide its own funds and in what conceivable sense is that rational or fair public policy, especially if it is the policy of the Administration?

The gentlelady from Rhode Island.

Ms. SCHNEIDER. I would like to discuss fairness and fees. There seems little question in my mind what is fair, and insofar as enabling the fishing industry to have the same type of arrangement that meat and poultry has is the only fair route to take.

When it comes to fees, it seems we have to look at where these agencies are right now in terms of capability of dealing with the challenge that we are discussing, with the inspection process, and it is my understanding that the USDA is the only agency at this time with the managerial experience in some of the field structure that is already in place to monitor the fish operations and the products.

So the differential in fees, by my way of thinking, knowing what we have in the USDA and what we might need if it were to go to the Department of Commerce or elsewhere, is enormous. A cost-benefit analysis would find it would be more cost-effective to put it in the USDA, where we have the field structure in place.

Neither FDA nor the Department of Commerce has as large a scale operation in place.

Mrs. Smith, you mentioned that USDA has a network for training for research and for enforcement and that you have experience with interaction with state programs, which is critical and also costly, but you already have that in place.

You also mentioned the importance and several of the witnesses mentioned the importance of the need to inform consumers and educate them about how to prepare the meat and the poultry.

Needless to say, that is expensive. Anytime we have an educational program—for the consumer, that costs money, but USDA already has that available. So as we look at what would be the most cost-effective way, given the data that we have been provided, I can't help but already personally reach a conclusion in that respect.

I have questions about not only our domestic concerns and the fees involved, but let's anticipate what kind of fees might have to be levied if we are talking about the overseas capability.

As we do a side-by-side comparison of those three agencies, it looks like USDA is the only agency with a credible overseas policy.

USDA does have foreign-based inspectors; is that right?

Mrs. **Smith**. I would like to ask Dr. Ron Prucha, who is the Associate Administrator for USDA's FSIS, to give you a direct answer to that question, since he has been there since its inception with poultry, and ask him if he would come forward, Mr. Chairman, if that is allowable.

Mr. **Studds**. Certainly.

Dr. **Prucha**. Foreign countries apply to FSIS for approval of their inspection programs. These are evaluated here at headquarters, and there are also on-site visits made prior to the approval or disapproval of a foreign inspection system.

If the system is approved, that country is allowed to export products to the U.S., and we monitor on a quarterly basis the plants that are approved under that foreign country's system.

At the present time there are approximately 42 foreign countries approved to export to the U.S., of which some 30 or so are actively exporting to this country. We do not have any longer resident foreign reviewers. They all travel out of the U.S. at the present time, but they are on site in those foreign countries approximately on a quarterly basis.

Ms. **Schneider**. Talking about foreign trade and its future, as was already pointed out, we are talking about a $2 billion industry in terms of export here in the U.S. and in terms of imports, fisheries products is third, after their automobiles and electronics.

So it has enormous importance in the global competitiveness marketplace, and as we look at some of the projects toward the future, it seems to me that we can anticipate both the imports and the exports growing.

And I think we need to keep this in mind when we determine which agency will take on that responsibility. I think that we also need to recognize that in 1992 the transformation that will be taking place in Europe is going to be critical to what we do in the U.S., particularly in the area of fisheries and many other traded products.

But the potential of trade barriers is one that we should anticipate and, as we look at that, I can't help but once again come back to USDA because of my knowledge of the work that you are doing there.

It seems like your responsiveness to international fish safety issues has been a major task that you have undertaken. So you have once again that infrastructure in place.

FDA doesn't have an overseas capability or extensive experience outside of their drug experience and the Department of Commerce has frankly low priority on fish trade issues, and no extensive experience reviewing some of the overseas inspection programs.

So from my point of view, I can't help but draw some conclusions that if our decision will be based on cost, clearly we ought to see what the bird in hand actually is. The FDA has mechanisms in place domestically. If we are looking toward growth in the international marketplace, then we have to see that there is a mechanism there that would not end up costing us much more.

Mr. Young.

Dr. YOUNG. If I could ~~please~~ provide comments now and in respect of time more comments for the record, I would like to point out in our opinion that FDA does have the exact programs in all the areas that you spoke to.

We have very extensive networks with the state at this time, and the milk shippers program is probably one of the best examples of a voluntary state-Federal interactive program that has markedly reduced the burden of disease in this product which is consumed even more on a per pound basis than meat, poultry and fish.

We have a number of memoranda of understanding with a variety of nations around the world, and I will submit some of these for the record. We also already have interaction with other departments, such as the DOD. I will submit for the record the memorandum of understanding under which we have collaborated with scientists based in other Government agencies and throughout the world.

[Copies of Memorandum of Understanding with foreign countries regarding shellfish and MOU's with other agencies regarding research programs for fishery products can be found at end of hearing.]

I think the record needs to point out that I believe that you are very familiar with the aquaculture programs in the FDA. However, one of my great laments is that we have not publicized our activities sufficiently. I shall submit for the record a description of extensive research activities in collaboration with NOAA and others. NOAA can speak for their types of inspections.

I will return now to the point that the entire food supply other than meat and poultry, which is under the aegis of the FDA, in excess of $350 billion a year plus all the drugs, $570 billion, we are strained with a budget that is somewhere around $550 million a year.

The issue is not can it be done. We have programs, but the problem is the funding. I think that in fairness, since we were discussing the fairness issue, I ought to probably state that for the record, and I will submit more if I could, please.

Ms. **Schneider**. I appreciate that.

My time is up. You know how it is with Members of Congress, we like to have the last word.

I did want to point out that considering that the American consumer has increased their consumption in the last 20 years by nearly 50 percent, so we see that the market is growing in the U.S., we also recognize the enormous international potential for a market.

What concerns me is that if we were in fact to say we are only going to levy a fee on the fisheries product as opposed to meat and poultry, that is unfair, and we would be cutting our own throats on a product that has potential to improve our balance of trade.

So it seems to me that what happens, what we are looking for, Mr. Chairman, I would call for a study to assess what infrastructures are already in place in these various agencies and could each provide us with a budget anticipating what it would cost you to undertake a fisheries inspection program.

It is frustrating to constantly be fighting on behalf of the fishermen because often when they ask for non-intervention on the part of the Government, everybody else gets a free ride and the fishermen get lost out to sea.

It was the same thing with the diesel fuel tax exemption that we had to take care of for off-road use for the fisherman. This is a case where it is in our best interests to be fair.

Thank you, Mr. Chairman.

Mr. **Carper**. [Presiding] Mr. Ortiz.

Mr. **Ortiz**. I am going to be very brief. Somebody discussed something about consumer confidence. I think it was Mr. Weddig. When we talk about consumer confidence, are we talking about—I am assuming the American consumer?

Mr. **Weddig**. That is correct, sir.

Mr. **Ortiz**. Are they more confident when they eat domestic products or foreign products? Has that determination been made?

Mr. **Weddig**. No, but in fairness, I suspect that the consumer typically doesn't know whether they are eating domestic or imported product.

Ms. **Haas**. As a consumer advocate for more than 15 years and having served as President of the Consumer Federation of America five times, I can tell you that in many instances unfortunately I am more confident in eating seafood from countries like Canada or Norway or Sweden that have mandatory fish inspection programs.

And I know when there is Canadian fish or when I see Norwegian salmon on the menu that that fish has been inspected, and I have more assurance in the safety and wholesomeness, and I would like to see the same for the American product.

Mr. ORTIZ. My next question would be does the consumer know when he is buying the product where it comes from, is it labeled?

Ms. HAAS. Unfortunately, it is infrequently labeled at the retail level, but I have been seeing it more and more lately, particularly with Norwegian salmon. But there is no consistency.

One of the problems that exists today is mislabeling, and without a mandatory inspection program, you don't have the assurance that you are getting what is on the label. And there have been some recent TV investigative reports around the country which have done tests, and we have had one in Washington where they bought fish at a Maine Avenue market and found that the fish was very often not what it was said to be.

Mr. ORTIZ. My next question would be in the same level.

Mr. Young, on these outbreaks, has a determination been made whether these outbreaks are caused by either a domestic product or a foreign product?

Dr. YOUNG. I don't have that data. Let me ask whether Dr. Archer has that.

No, but we can go back to CDC and see whether we can get information on that, and I will provide what we have for the record.

[The following was supplied for the record.]

The Food and Drug Administration has no information that will indicate whether the illnesses that have been reported were caused by either domestic or imported products.

Mr. ORTIZ. I think we should advise the consumer and put labels on so they are aware because we are talking about the confidence of the consumer, and they don't know what they are eating and what is causing these diseases.

Thank you for being with us today.

Thank you, Mr. Chairman.

Dr. YOUNG. Thank you. I thank you for your comment on labeling.

Mr. CARPER. I would like to try to pull everything together in my mind.

First of all, four questions closely related.

Do we have a serious health problem here?

Second question, is the current system that we have for reducing those risks, is that adequate? If not, who should have the responsibility for making it adequate? How do we pay for those improved safeguards?

And why don't you go first, Ms. Haas.

Ms. HAAS. Thank you, Mr. Carper.

To begin with, yes, we do have a very serious health problem. I think whatever way you look at the data and statistics, there are unnecessary illnesses that occur from eating fish and shellfish.

Your second question—do we have an adequate system? No. I think it is important that the data that was debated here today was the data about illness incidents. There was no debate about the inadequacy of our current programs.

I find that interesting, that we see that a minuscule amount of the fish and shellfish that should be inspected is being inspected, and that the programs are too often voluntary.

The third question was who should do it, which I answered earlier. I think that each of the agencies and each of those who have testified today have a real commitment to protecting the public health, and I think that each of them have responsibilities that I respect.

I think that the resources, the history, the infrastructure, the research capabilities and the relationship to nutrition and the Human Nutrition Information Service seems to us that the most appropriate place is the Department of Agriculture.

I do at the same time believe that the responsibilities for chemical contaminant monitoring that the FDA has handled needs to be improved, and I think should be retained. I think that it should be from appropriated funds.

This is a public health program and it would be a great deviation from any other kind of public health program to have it paid for by those who are the industry. I see no reason to do that now.

Mr. CARPER. Thank you.

Mr. Weddig.

Mr. WEDDIG. Thank you, sir.

We do not have a serious health problem with seafood. We have sporadic health problems that are in isolated parts of the industry, but overall the seafood supply is very safe. But for the person who is—the individual who is affected by one of the sporadic incidents, it is a very serious problem, and we would like to minimize to the greatest extent possible any likelihood of someone becoming ill from our products.

Is the system adequate? Many elements are, but what we see as inadequacy is primarily putting it together in a comprehensive form and eliminating some of the duplication and expanding areas that need attention such as monitoring the environment for toxic substances.

To illustrate, one of the frustrations that we have right now, one of the incidents that prompted us to get into this several years ago, was the situation of packers reporting FDA comes in one day and tells us how to do it.

USDC comes in the next and tells us something else, and the third day another agency tells us how to do it, and that is a third way that is being employed.

We do need a single agency responsible here that is totally coordinated.

Mr. CARPER. Who should that be?

Mr. WEDDIG. In our mind, all three of the agencies have very valuable experience and expertise. We think there is some downside for each of the three agencies as well, but our initial analysis would indicate that a comprehensive program of the type we are envisioning would best be served by the Department of Agriculture at this time.

We are willing to look at this carefully and to work with whatever agency the Congress chooses to perform this task, but at this time we think the call would be towards the Department of Agriculture.

How to pay for it, simple fairness would dictate that as long as inspection is being paid for from appropriated funds for meat and poultry products, that it should be the same for us.

One other point why this is important, the concerns that we have are primarily due to degradation in the environment. These are societal problems. Society chooses not to spend the money to fix the sewage disposal plants, to allow medical wastes, not to clean up Boston Harbor.

Society has chosen to allow the dumping of toxics into the ocean, not to monitor carefully oil transport. Therefore, we think our society should pay for taking care of the outcome of all of these ills.

Mr. CARPER. Mr. Brennan.

Mr. BRENNAN. I agree that there is not a serious health problem with respect to seafood. On the other hand, I agree with what—with much of what Ms. Haas says. I think the system, in fact, does need improving.

As the Chairman had said, one unnecessary death is one too many, and I agree with that. I believe that as we have increasingly sophisticated consumers who are eating fish because of its health benefits, they have a legitimate right to expect that that product will be clean and wholesome.

To the extent that they don't have full confidence in the food supply, particularly with respect to fish, we should take actions to give them that assurance. There is no way that any particular food can ever be guaranteed 100 percent to be wholesome in every case.

You have to guard against improper handling in the home and in processing and in harvesting, and mistakes will happen in any food commodity. But I believe that we are pretty close to a good system, but it needs to be improved. I absolutely agree with that.

The current system is not adequate. How to make it adequate—I think as I have said earlier, you have to look at the industry itself, which is a different type of industry than the red meat and poultry industry, and it has to be addressed by taking into account the peculiarities of that industry.

Let me also point out, Ms. Schneider has left, but I do want to state for the record that the only agency in the Federal Government that has inspectors in a plant inspecting seafood product on a 24-hour basis if necessary is the National Marine Fisheries Service.

We do that for a fee. We inspect about 11 percent of the product that is consumed in the U.S. We are the only agency that has observers and inspectors on board fishing vessels. We are the only agency that regulates the taking of fish from the oceans.

And it seems to me it is kind of ridiculous to have one inspector on board a factory processor looking to see how the product is brought aboard——

Mr. CARPER. Let me say how to pay for an improved system?

Mr. BRENNAN. The Administration's position clearly is that funding for any increased seafood inspection activities should be paid for by the industry through user fees.

Mr. CARPER. Dr. Young?

Dr. YOUNG. Thank you very much. I do not think that we have a serious health problem with fish. I must emphasize as clearly as I can that it is imperative to look at every type of illness.

Mr. CARPER. Fin fish or shellfish or both?

Dr. YOUNG. I would say that we have no substantive problem with fin fish. I think on a per flesh eaten, our greatest problem is with raw shellfish. If one ate chicken, turkey or beef raw, one would have an equal problem.

The issue is raw, and in that fashion, not the shellfish itself.

Secondly, is the program adequate? I do not believe it is. I lament as you did and others have the overlapping patchwork. I think we can do a better job of coordination. I believe we need to have a greater degree of inspection.

I support the comments made by NOAA that while we have some experience in this in NOAA and in the Food and Drug Administration, we do not have an integrated program at this time.

Funding has been a problem. Who should have this responsibility? I don't believe that the Administration has its position at this time, and I will not go into comparisons. I would only say that there are strengths and weaknesses in each agency.

Our greatest mission is that of public health. In that sense, when one is concerned about eating fish and all sorts of products, this is essentially a health issue.

I should point out that there are three fundamental areas in public health that can lead to the greatest improvement in quality and length of life. One deals with smoking. The second is substance abuse. The third is diet.

Low-fat foods have been shown to have a great impact on increasing longevity and decreasing disease. And I want to leave the impression very strongly that fish, among other foods, are a very fine source of protein, and we should not overlook that fact.

Who should pay? I believe we have got to balance off the appropriation issue with the fairness issue, and the Administration is focusing on that at this time. We do not have a position other than the point that Mr. Brennan mentioned.

Mr. CARPER. Mrs. Smith?

Mrs. SMITH. We do not feel that we have as defined here a serious problem. Certainly inspection would improve or lessen that problem.

Is the current system adequate? Our concern is that the current system has voids in it and, as you look at it, you need to define what adequacy is and what adequacy is not. As demand increases, then certainly it is going to become less adequate with more movement of product.

How do we pay? We certainly feel that it is a consumer health issue, a safety issue, and in that respect we have not totally come down on a black and white yes or no here, but our record has been that those consumer-driven health and wholesomeness issues are borne by Government in inspection.

Mr. CARPER. Did you say what agency should take the lead in upgrading the quality of the work?

Mrs. SMITH. I did not say. We feel that certainly USDA has a track record of inspection throughout this country and monitoring in the foreign market and certainly that same system could apply very readily or more readily in inspection of the seafood as we look at increased inspection.

Mr. CARPER. My thanks to all of you for your responses.

Mr. Tallon, the gentleman from South Carolina.

Mr. TALLON. Thank you very much, Mr. Chairman.

Mrs. Smith, as you know, mentioned a proposal for less than continuous inspection of certain meat facilities, recently raised quite a controversy and actually led to withdrawal of proposals for implementing it.

How would you propose to implement a less-than-continuous system for seafood in light of this?

Mrs. SMITH. Well, you have heard the discussion on the terminology "continuous," because it would be very difficult to certainly inspect every fish, and we do have, of course, the experience on record here with HACCP of ways that you identify critical points of inspection and flow, et cetera.

Let me just say that we were looking—at USDA, the concerns and issues were raised as to what are we monitoring today, what are you trying to do in meat and poultry inspection? Along with time and modernization of equipment and technology, we are trying to put into place, of course, something that will—and we have the system and have the technology and the equipment today to monitor residues.

Until 1966, we didn't in inspection monitor any kind of residues. The microbiology gamut is wide open. We wanted to do more than do visible inspection of meat and poultry, and this is certainly true with fish also.

Mr. TALLON. Maybe you could tell me, Mrs. Smith—you might want to comment on it again—how this legislation is similar to the inspection parameters and procedures that are mandated for our meat and poultry industries.

Mrs. SMITH. Here again, I think the issue is what is the total scope of the inspection, and it is certainly like what we are doing currently with meat and poultry, and it would be up to this Committee and Congress to define very clearly what you want inspected in fish inspection and shellfish, because it is a different type of product.

And in your definition of inspection, certainly we want to make sure that overall we provide to the consumer a safe and wholesome product. And with inspection, you can more readily do that.

And with the overall food safety issues today, certainly that is a real concern of all of us.

Mr. TALLON. Thank you, ma'am.

Mr. Chairman, I am not sure what—Mr. Carper, I am not sure what you were asking Dr. Young.

Mr. CARPER. I was asking if he was a doctor or a mister.

Mr. TALLON. We got that. I am referring to him as the honorable doctor.

Dr. YOUNG. I put my pants on one leg at a time like anybody else. You can call me mister or doctor, take your choice.

Mr. TALLON. You were talking about public health problems a few minutes ago, and you mentioned smoking and substance abuse. I am not sure—you were talking about public health.

The third problem had to do with some sort of food. What was the problem you were discussing and what sort of food?

Dr. YOUNG. I was trying to, in respect for Mr. Carper, go as fast as I could. I apologize.

Mr. TALLON. We are on my time now.

Dr. YOUNG. From a public health standpoint, we look, as public health physicians, in trying to reduce the large areas of disease. By saying this, we are in no way overlooking any of the other problems.

But if you look at ways in which we can prevent disease, if you remove smoking and substance abuse, and here I am talking about primarily alcohol, which is our larger problem, and ask what can the person who doesn't smoke or doesn't drink do to extend his or her life, the answer is diet modification. Reduction in fat in the diet will have the largest impact.

Now in this sense, fish is an outstanding product. That is the point that I was trying to bring out. If you look at fish and compare it to poultry, which is the other low-fat product, and I am not trying to distinguish from beef, which also can be modified in a variety of ways, focusing just on poultry, that under those circumstances, looking at all the data taken together, you are less likely to have an illness or a death from the current system, let alone any improvements per person per pound with fin fish than you are with chicken.

Now there is a problem with eating raw shellfish, and that is related to the rawness of the product, and you would have the same with eating raw chicken. We have done some very nice experimental work in concert with the National Institute of Aging—in looking at rodent studies, one can improve the life span of an animal, decrease disease by both caloric restriction with balanced vitamins, and that is a lower-fat diet.

My point is that focusing on these three are very important and fish is an essentially important portion of that diet.

Mr. TALLON. As an expert, your testimony I find very interesting. I think that as far as life expectancy is concerned and general health, that poor diet could be as detrimental as smoking to health.

Dr. YOUNG. You are absolutely correct. The diet is fundamental—the Secretary of the Department is extraordinarily interested in this, and we are trying to look at ways to get an integrated nutrition program that will help each of us not only extend life but improve the quality of life.

One can reduce heart disease, reduce some of the burden of cancer. These are important issues.

Mr. TALLON. I think we hear every day constantly over and over again the concerns as far as smoking is concerned and public health and life expectancy, and I wish that Members of Congress, public policy makers, would focus also on some of these other areas and certainly diet concerns.

I appreciate your comments.

Dr. YOUNG. We will certainly do that.

I will submit for you a portion of our management plan, Phase 3, which focuses on diet and nutrition as the integrated highest priority of the agency when it looks at a center focus.

I will provide that for the record because I do believe that we have overlooked this from a preventive measure on preventing disease, and it is something we need to concentrate on.

Mr. TALLON. I appreciate you saying that. I think that we kind of over-focus on some areas that may be obvious and not to think about the concerns of proper diet and the negative impact that has on public health and life expectancy.

Thank you very much.

Mr. **Pallone**. Thank you, Mr. Chairman.

I just wanted to ask briefly about the shellfish sanitation program. I have seen some of these reports that the FDA puts out on an annual basis where they evaluate the states' programs, and I know what Ms. Haas brought out. Something I have seen from my own experience is that oftentimes the same objection is nonconformity in the states' programs, repeated year after year. My initial reaction is that because this system is voluntary there is really no teeth in it in terms of forcing states to conform and to upgrade. I know Ms. Haas said that there seems to be even more of a problem in trying to get the states to make the improvements today than there might have been a few years ago.

Has anyone yet commented at the hearing or would Mr. Young perhaps like to comment on making participation mandatory by states and having perhaps the FDA have some teeth to the program so that they can force improvements, because it seems to me, we need to do something in that regard. Otherwise we don't have any guarantee that there is going to be any upgrading.

Dr. **Young**. I think you have hit the nail right on the head. There is some real problems that Congress can fix by dealing with certain aspects of authorities. Let me run through a few of these:

First, it is difficult to find where all these plants are. There is not a registration program.

Second, if one is going to look at the HACCP concept, which we strongly support—we have been involved in working with NOAA on this. Actually this is the same program that was used in low acid canned food. You have to have the ability to look at the records. If you can't look at the records, you can't determine whether good manufacturing practices are followed.

Third, regrettably—and this is the point dealing with bootlegging that Mr. Weddig raised—I believe that part of the penalties are a joke. You catch somebody that is bootlegging shellfish, and really you are dealing with a few hundred dollars fine or something like this, and there is not the penalties that need to be provided.

Looking at the penalties for enforcement issues, one is moving toward the Lacey type approach, in which we deal with collaboration.

Mr. **Studds**. Excuse me for interrupting. We have a personal message. Is Mr. Ron Pruka—P-R-U-K-A—in the room? Please check with the Committee staff member right here. It is an emergency. I apologize.

Dr. **Young**. Certainly, Mr. Chairman, Thank you for your interruption on that. The penalties need to be strengthened in our opinion. Instead of dealing with bootlegging and as a matter of fact, other problems, a few hundred dollars, going with higher penalties would be important. I think also we need to have the ability to put, just as you said, more teeth into the program in regards to violation in shellfish on intrastate basis. Here it is a very complicated and tortured way to deal with this at this time, but we have been working with some of the programs with NOAA, with states in trying to deal with it, but it is much harder than if that authority was directly provided.

I think these things can be done by congressional action. I would be happy to staff you in any ways that you would that you would feel appropriate to give you a much more detailed analysis. But these things would make a difference.

Now, with shellfish there is no question that the likelihood of death from either hepatitis or vibrio vulnificus is much higher. That is why we felt that looking at the harvesting waters is a very important point.

When it comes to the issue of what is done year by year, we have brought up the threats of delicensing and decertification. We have delicensed, and in the New York Times, just one or two days ago, there was a terrible concern on the State of Connecticut to identify the state, because it was identified there, with how are they going to bring their program in compliance, and in that case, they were put on notification and the other states have raised that point through the volunteer program.

But I think there are ways that we can strengthen it. I do believe that the consumer requires that these products are really safe and wholesome. It is an important fundamental aspect of our health system, so I think things can be done. I think there is a lot of fine tuning, and some major modifications, but I believe that we would leave an injustice to the fishing industry if it was left as if these products are grossly unsafe and that they are poisoning the American people. That is why I wanted to particularly focus some time on the health issues.

And again, I would be happy to work, through CDC or NIH, or other health organizations, to provide and to bring the types of consensus that the chairman requested in regards to the health issues themselves.

I gather you have already brought this up. If we could—if I could ask through you that I could ask some additional questions of Mr. Young, in a written form, I would appreciate that.

Mr. STUDDS. That will be okay.

I want to thank you all.

Don't panic, Some of you have been bursting to interject. I am going to give each of you a chance to highlight or to summarize or if you want to mention something that you think was insufficiently emphasized. This is—I am not going to have steak tartar for lunch. This has been a disturbing——

Dr. YOUNG. A wise decision, sir.

Mr. STUDDS. But I am damned if I am going to cut out the oysters and the clams.

Dr. YOUNG. That is your decision, sir.

Mr. STUDDS. Mr. Weddig, I will refrain from the temptation to point out that it wasn't society that dropped the money for Boston Harbor from the project. Let me just say it looks to me that in some very critical regards we do have a consensus. To the average citizen it would look like we should proceed immediately, because we all agree on what we need to do with a couple of minor exceptions.

The problem is in Washington minor exceptions more often than not, are lethal to an idea. It would appear that for a whole variety of reasons, some of them more or less real, some of them more or less problems of perception, there is a consensus ranging from those who speak for consumers to those who speak for the industry, and everybody in between that we probably need to do more than we are doing, and we probably ought to do that sooner rather than later.

Wherever on that spectrum you fall, and some of you fall at different ends of the spectrum in terms of reality of the problem versus perception of the problem, you put it together and you have a problem. Everybody agrees. We need to act. If you are just a citizen, you might say, okay, Congress, act. Don't just sit there talking about it, do something. Well, we all apparently agree on that, with variations on the theme.

The problems that remain are the lack of consensus that remains is relatively minor and procedural—who should do it and who should pay for it.

Ms. HAAS. You consider those minor?

Mr. STUDDS. Well, it is certainly minor if you are just John Q. Citizen and you acknowledge and your legislators acknowledge and the Executive Branch acknowledges there is a problem that needs to be dealt with. We all know more or less what to do about it. It is the simple problem of delegating the responsibility to do it and finding the money to pay for it.

That is what folks in Washington do all the time. What is the problem? The problem is hard to explain to a citizen. The problem is that we have at least three agencies of the Government who have some arguable case for undertaking whatever new responsibilities that we decide to give the Executive Branch, and although none of the three is allowed to say so, I suppose that each of the three would love to do it.

That is one of the reasons the Administration doesn't have a position. One of the reasons. Ms. Haas and Mr. Weddig both know where in this bureaucracy they would like to place the responsibility. My guess is that although they would not say it, the bureaucracy probably had some colorful conversations among themselves as to where the responsibility most logically ought to lie.

I confess that I don't really know the answer to the question. If somebody gave me a magic wand and said which one of the agencies would you entrust with it, I am not entirely sure. I can make some strong cases for each of the three as each of you have done. Then comes the only other minor problem remaining, and that is how to pay for it.

This Administration, insofar as it has ideas, believes that other people ought to pay for them. I don't know how we are going to do it with environment precedents and the educational precedents and everything else. We don't have any money, at least not under the rules which we are told we have to play by, which means we can't raise any more money.

Therefore, we get positions like that which the Administration witnesses have been compelled to give today. We should do it, and someone else should pay for it, notwithstanding questions of equity and fairness, and almost irrationality in terms of public policy in the food producing sectors of the country.

If the public can come up with an answer to that, it would facilitate the situation here. It wouldn't solve it, because the same controversy and indecision you have within the Executive branch obviously is mirrored in the Congress where the legislative jurisdictional squabbles persist in their conventional fashion.

So we have those two problems remaining to be resolved, and I am not going to speak for all of you because I am going to give you a chance to summarize for yourselves. I would be interested in what you are going to say in your allotted two minutes, unless the bells ring.

Would you agree with the essence of what I have just said, that we need to act. In a broad sense we have some consensus about what it is we need to do, and the remaining problems of any consequence at all, or questions of any consequence at all, are who should do it and how should it be paid for.

But use your final minute or two to highlight whatever you think needs to be highlighted and by way of summary.

Ms. Haas.

Ms. **Haas**. Mr. Chairman, that was a very eloquent summation of a very critical problem.

From the perspective of consumers, I think that it is important that we not continue to expose consumers needlessly to risks that can be prevented, that can be prevented only with a mandatory inspection program like we have been discussing. I would hope that the Congress did not get bogged down in a tough battle, nor the Administration, because I was very moved after some of our research to be contacted by citizens who lost members of their family who died of these food poisonings, whether it is scombrotoxin poisoning or other illnesses, because of situations that could have been prevented if we had certification of fishing vessels that ensure that there was icing on those boats.

I would just like to say one thing, that I have been eager to answer the data that Dr. Young has presented.

You cannot remove shellfish, which is one of the most important causes of the problem, from any kind of discussion about the seriousness of the problem. Just like you can't remove hamburger from beef statistics. You can't remove turkey from poultry, and I think it is unfair to the discussion to conclude without realizing the total problem, and that is of both fin fish and shellfish, and both of those require a mandatory fish inspection program. The sooner the better, and citizens are looking really for results from Congress, and I think that that will restore the confidence that Mr. Weddig seeks on the part of the industry, that the agencies certainly seek on the part for the citizens of this country, and I look forward to working with you in seeing that legislation move through Congress.

Mr. **Studds**. Thank you very much. Thank you for the role you played in this whole struggle. Mr. Weddig?

Mr. **Weddig**. Thank you, Mr. Chairman. I think we have said pretty much what we want to say and what we believe——

Mr. **Studds**. Final statements aren't compulsory, just an opportunity to emphasize something.

Mr. **Weddig**. OK. I would like to make one minor point so there is no misunderstanding among the members of the press who may still be here, but in this constant reference to shellfish, I hope they understand that what they are talking about are raw mulluscan shell fish and that there is another kind, crustaceans which do not have that type of problem, and——

Mr. STUDDS. Don't even raise the subject.

Mr. WEDDIG. Anyway, I would like to make sure that is understood here. The only point I would want to address finally, then, is this question of paying for it. We made our point about fundamental fairness and all that, but in one respect this hearing on this process is moving ahead of schedule in the sense that there is underway a very substantial investigation, and part of that is an economic analysis that perhaps might more clearly define just what a program would cost.

We have heard estimates of 30 to 100 million dollars. That is a fairly wide range of money. I think the question of how it would be paid for might more easily be addressed once we have a more precise understanding of what the costs are, and we are hoping that the legislative process here will move somewhat in tandem with the completion of the economic work so that we know for sure what we are really talking about when the costs have to be addressed.

Mr. STUDDS. Mr. Brennan?

Mr. BRENNAN. Mr. Chairman, I have very little to add to your summation. I think it clearly captures the spirit of the discussion today. Just let me say that the agencies are working together and talking with each other and cooperating and looking for the best solution. I have really been pleased with the way the Food and Drug Administration and the Department of Agriculture and my agency have addressed this because they are concerned about solving a problem, and turf may be lurking in the background, but it really is based on honest differences as to how the problem should be addressed.

Let me just say for the record, National Marines Fisheries Service is not suggesting in the Administration discussions that the National Marine Fisheries Service should take over the entire burden. It is a question of—it clearly is a question that there has to be involvement by either the Food and Drug Administration or the Department of Agriculture, and we want to participate appropriately.

Mr. STUDDS. Thank you. Dr. Young, I assume you are sending a diplomatic note to Japan immediately with respect to sushi.

Dr. YOUNG. No. I would just like to make a few remarks in closing. First, I believe that the role of Government is to serve the people and to provide the best possible programs to meet real and perceived needs.

Therefore, I think that type of program that can best be fashioned is the work that we are already undertaking, the three agencies are working together. This is not the first time we have been discussing these issues, and I think a company operation among many partners provides a way to deal with this, not only in the Congress, but the Administration and the industrial and consumer sectors as well.

You can certainly have the Food and Drug Administration's pledge to do so. In dealing with the program it does have to be multifaceted. You have to deal with water quality and pollution control, harvesting and processing. We also have to focus on the issues of storage and distribution and sales and retailing and research and education.

This is not a single light switch program. I would also like to leave in conclusion that while there are problems of safety with everything that we consume that on balance, fin fish is a very important portion of our diet and is a relatively safe product.

I do distinguish, and here is probably the only major spot that Ellen and I will part company on. I do distinguish greatly between molluscan shellfish that are eaten raw and the risk associated with that than the risk associated with fin fish.

Now adding back to your original comment, the reason that I would not send the diplomatic note, besides not trifling in another nation's internal dietary patterns is that there is a fundamental difference between fin fish and molluscans. Molluscans do concentrate microbes and bacteria, including bacteria and viruses, and one is consuming the gastrointestinal tract as well as a muscle, and you must remember that you are eating the entrails.

Mr. STUDDS. You are talking to somebody—you don't have to say that again.

Dr. YOUNG. Well, I am sorry you asked the question, sir. Now if you look at those issues, and you do divide them and they fall nicely into two different types of products, and in that sense I believe you can explain in part the health differences.

Now, having said that, I would not in any way come in with the Food and Drug Administration badge, sir, and seize your oysters as you are about to consume them.

Mr. STUDDS. And I assume you will join us for a plate thereof.

Dr. YOUNG. I am sorry, I didn't hear that.

Mr. STUDDS. Will you join us? Never mind.

Dr. YOUNG. I have a poem if you would like to hear, too.

Mr. STUDDS. Thank you very much. Mrs. Smith, you get the last word.

Mrs. SMITH. Thank you, Mr. Chairman. Let me say that we are committed to delivering to the consumer a safe and wholesome food supply at USDA. We want to be a part of the solution, not the problem. I again commend you and the manner in which you have held this hearing.

It is an issue. We don't have all the answers. We will provide information and anything that might be of value to your Committee and to Congress in order to make the decision.

I appreciate the opportunity of being here today, and I, too, would like to say that it has been, as a new kid on the block, it has been heart-warming to see the cooperation between the agencies as we have studied the problem and as we have worked toward trying to come up with a solution to bring to you today, and we are committed to continue that dialogue and hopefully we can help frame the tool that will help the solution and provide the consumer with a product that has been inspected and can be assured to be safe.

Mr. STUDDS. I appreciate that. I want to thank everybody here on the panel. Obviously, as we proceed in the weeks and months ahead, each of you and the agency and the groups for whom you speak is going to be critical. We are going to look forward to working with you.

Thank you for your time, effort and patience. The Subcommittee stands adjourned.

[Whereupon, at 12:17 p.m., the Subcommittee was adjourned, subject to the call of the Chair.]

[The following was submitted for the record.]

STATEMENT OF HON. NANCY PELOSI, A U.S. REPRESENTATIVE FROM CALIFORNIA

Mr. Chairman and Members of the Subcommittee, thank you for conducting this hearing today. The topic of fish inspection for the seafood industry has reached a new level of importance. The growing concern about food safety and health risks for consumers makes this a timely discussion.

The U.S. commercial fishing industry plays a vital role in our national economy. In the last decade the U.S. per capita consumption of seafood increased from 11.0 pounds to 18.7 pounds. Within the past decade, seafood has become the fastest growing sector of the U.S. food market. The United States is now the world's largest exporter of fish. In addition, two-thirds of the seafood consumed in the United States is imported.

We do know that there is great nutritional value in seafood. We do not know if fish from contaminated waters is being made available to consumers or what health effects might result from any possible contamination. Fish exposed to water pollutants, such as PCB's, can have a very long-term effect. Dr. W.R. Swain reported in the *Journal of Aquatic Toxicology* that it would take five generations for an individual's initial PCB levels from fish ingestion to disappear within a family. In the case of shellfish, PCB levels can become more concentrated, sometimes as much as ten times higher, than the levels in fish.

There is a strong need for Federal inspection and protection. The Centers for Disease Control reported that ten percent of all food-borne disease outbreaks were attributed to fish and shellfish between 1973 and 1984. A National Marine Fisheries Service study reports that "90 percent of all reported seafood outbreaks are restricted to very few species of fish and shellfish." While it is clear that this food product is without a strong oversight program and that there is a need to develop an inspection program, the seafood industry will not be easy to oversee because of its diverse activities: Fishermen may not be aware of the water quality where they are catching fish; there is little control over what the fish are consuming; monitoring fish quality also means monitoring water quality and process sanitation. Naturally, with any enforcement program, there is the question of sufficient funding to make the program effective.

San Francisco is currently embarking on a dramatic but practical approach to confronting the problem of seafood sanitation and inspection. A Seafood Center is underway which would serve as a model offering the latest technology for the Nation's seafood industry. This plan incorporates fish handling and processing facilities with a Fisheries Institute that will include seafood sanitation inspection laboratories, test kitchens and a Government monitoring and advisory services center.

A key component of the Seafood Center is the development of facilities that will readily meet the Federal sanitation guidelines when they become effective.

It is apparent that a gap exists between serving the consumer and serving the consumer well. I applaud your efforts to look at the area of seafood inspection. As a representative of a coastal district that is home to an active commercial fishing community, I am also interested in supervision of the seafood industry and in the delivery of a safe, guaranteed product for human consumption.

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101st CONGRESS
1st Session

H. R. 1387

To provide for the inspection of all commercial seafood destined for human consumption in the United States.

IN THE HOUSE OF REPRESENTATIVES

March 14, 1989

Mr. Dorgan of North Dakota (for himself, Mr. Stenholm, Mrs. Boxer, Mr. Vento, Mr. Johnson of South Dakota, Mr. Smith of Florida, Mr. Owens of New York, Mr. Fauntroy, Mr. Levin of Michigan, Mr. Torres, and Mr. Foglietta) introduced the following bill; which was referred jointly to the Committees on Merchant Marine and Fisheries and Agriculture

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A BILL

To provide for the inspection of all commercial seafood destined for human consumption in the United States.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

Section 1. This Act may be cited as the "Mandatory Fish Inspection Act of 1989".

Sec. 2. (a) The Secretary of Agriculture shall initiate, within one year after the date of enactment of this Act, a mandatory program under the Department of Agriculture for the comprehensive and statistically representative inspection of the commercial processing of all freshwater and saltwater fish, shellfish, and their products, used for human consumption.

(b) The mandatory program should be similar, to the extent practical, to the currently effective system for the inspection of commercially processed meat and poultry.

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101st CONGRESS
1st Session

H. R. 2511

To direct the President to develop a comprehensive safety program to ensure the quality and wholesomeness of all fish products intended for human consumption in the United States.

IN THE HOUSE OF REPRESENTATIVES

May 25, 1989

Mr. Studds (for himself and Mr. Young of Alaska) introduced the following bill; which was referred to the Committee on Merchant Marine and Fisheries

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A BILL

To direct the President to develop a comprehensive safety program to ensure the quality and wholesomeness of all fish products intended for human consumption in the United States.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Consumer Seafood Safety Act of 1989".

SEC. 2. FINDINGS AND PURPOSES.

(a) Findings.—The Congress finds and declares the following:

(1) Seafood constitutes an important component of the Nation's food supply. Domestic and imported fish products are consumed throughout the Nation, and are harvested and marketed by a large, diverse commercial industry.

(2) Heightened awareness of the health benefits associated with seafood and greater diversity of fish products have raised consumption rates and increased the demand for wholesome, high quality seafood.

(3) The sale of poor quality, unwholesome, contaminated, adulterated, mislabeled, or deceptively packaged products is hazardous to the consumer and detrimental to the commercial fishing industry and interstate and foreign commerce.

(4) Current systems of inspection and monitoring are insufficient to ensure public confidence in the wholesomeness, safety, and quality of all fish products.

(5) Existing Federal standards are inadequate to maintain good seafood handling and manufacturing practices, to ensure consistent fish product packaging and labeling procedures, or to detect hazardous levels of contaminants in fish products.

(6) More information on the safety, wholesomeness, and health risks of seafood would benefit the consumer and the commercial seafood industry.

(7) The Federal Government has the responsibility of ensuring the safety and quality of all fish products sold in interstate commerce for consumption in the United States.

(b) PURPOSES.—It is declared to be the purposes of the Congress in this Act—

(1) to ensure the safety of all fish products in the United States; and

(2) to maximize the health benefits of consuming seafood, enhance public confidence in the wholesomeness and safety of fish products, and protect the seafood market by requiring the development of a comprehensive safety program, including—

(A) the mandatory inspection of all fish products;

(B) the establishment and enforcement of safety standards for fish products;

(C) the evaluation and monitoring of fish product safety and consumer health risks; and

(D) the design of consumer education programs.

SEC. 3. ESTABLISHMENT OF SEAFOOD SAFETY PROGRAM.

Not later than one year after the date of the enactment of this Act, the President shall establish a seafood safety program for all fish products sold in interstate commerce in accordance with this Act which is designed in consultation with the National Marine Fisheries Service, other appropriate Federal agencies, and representatives of the seafood industry and national consumer organizations.

SEC. 4. PROGRAM FEATURES.

The seafood safety program established pursuant to this Act shall include the following:

(1) MANDATORY INSPECTION.—Mandatory inspection of each fish product covered by the program in accordance with the Hazard Analysis Critical Control Point method under procedures which—

(A) are specifically designed for each fish product;

(B) take into account the recommendations of the National Marine Fisheries Service Model Seafood Surveillance Project; and

(C) encompass the harvesting, processing, storing, transportation, and marketing of each fish product subject to such inspection.

(2) FEDERAL STANDARDS.—Establishment of Federal seafood standards, including—

(A) standards for maintaining sanitary conditions and good harvesting and manufacturing practices on fishing vessels and in processing plants;

(B) minimum standards for wholesomeness, grading, packaging, and labeling of seafood, including the use of designated common names for various fish products; and

(C) standards for acceptable levels of contaminants in fish products.

(3) ENFORCEMENT AND MONITORING.—Establishment and implementation of methods for enforcing the program, including—

(A) procedures for enforcing the program, including product detention and embargo;

(B) designation of enforcement officers who shall have the authority to enter any seafood processing or manufacturing facility for the purposes of conducting inspections, including taking fish product samples and accessing records;

(C) establishment of Federal fish product monitoring systems to provide reliable records on fish products (including incorporation of existing State systems), including the documentation of fish product origin, transportation, and processing history;

(D) establishment of a Federal monitoring system to provide reliable data on seafood-related consumer health risks, including collection and dissemination of data on the number, causes, and geographic location of seafood-related illnesses; and

(E) establishment of a sampling program to monitor and regulate contaminant levels in fish products, including adequate sampling, reporting, and recordkeeping to ensure the effective tracing of contamination sources.

(4) RESEARCH.—Establishment of priorities for seafood safety research, such as test methodology for biological and chemical contaminants, and directing appropriate Federal agencies to fund research regarding those priorities.

(5) EDUCATION.—Design and implementation of national programs for seafood safety education, including designation of regional and national seafood safety centers which shall conduct, support, and foster research, investigation, experimentation, education, and training in seafood safety-related areas.

SEC. 5. INTERACTION OF STATE, FEDERAL, AND FOREIGN SAFETY PROGRAMS.

(a) CONSISTENCY WITH OTHER PROGRAMS.—A seafood safety program established pursuant to this Act shall be designed and implemented, to the extent practicable, to be consistent with existing Federal and State programs for ensuring the safety and wholesomeness of seafood.

(b) No Preemption.—Nothing in this Act may be construed to preempt or supersede any program relating to fish product promotion established and operated under existing Federal or State law.

(c) Arrangements With Foreign Nations.—The President shall encourage appropriate technical arrangements with foreign nations to ensure mutual acceptance of seafood standards and inspection services.

SEC. 6. DEFINITIONS.

In this Act—

(1) the term "contaminant" means any substance which is hazardous to human health when ingested, and includes—

(A) such chemicals as heavy metals, pesticides, and polychlorinated biphenyls;

(B) such parasitic organisms as bacteria and viruses; and

(C) such natural microbiological toxins as ciguatoxin and scombrotoxin;

(2) the term "fish" includes all finfish, mollusks, crustaceans, and other forms of aquatic animal and plant life, whether from wild or cultured sources, except birds and mammals;

(3) the term "fish product" means any food product intended for human consumption in the United States and derived in whole or in part from fish, including unprocessed fish;

(4) the term "interstate commerce" includes—

(A) the transportation into any State of any fish product from outside that State; and

(B) receipt of any fish product from a vessel located in the exclusive economic zone;

(5) the term "Hazard Analysis Critical Control Point method" means the system of food inspection described and endorsed by the National Research Council in the article entitled "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients", as published in May, 1985 by the National Academy Press; and

(6) the term "seafood" includes all domestic and imported marine and freshwater fish products intended for human consumption in the United States.

SEC. 7. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated $90,000,000 to carry out this Act for each of the fiscal years 1990, 1991, 1992, and 1993.

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PUBLIC VOICE
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TESTIMONY OF ELLEN HAAS
EXECUTIVE DIRECTOR
PUBLIC VOICE FOR FOOD AND HEALTH POLICY
BEFORE THE HOUSE MERCHANT MARINE AND FISHERIES COMMITTEE
SUBCOMMITTEE ON FISHERIES AND WILDLIFE CONSERVATION
AND THE ENVIRONMENT
ON THE NEED FOR A MANDATORY SEAFOOD INSPECTION PROGRAM
JUNE 7, 1989

Chairman Studds, members of the Subcommittee, my name is Ellen Haas. I am the Executive Director of Public Voice for Food and Health Policy, a national non-profit consumer research, education and advocacy organization working on issues of health, nutrition and food safety.

I appreciate the opportunity to appear before you today to document the serious health risks to consumers in our seafood supply and the inadequacy of current federal and state inspection programs which leave consumers vulnerable to acute illnesses, sometimes death, as well as to risk of cancer.

Since 1983, with our publication of "A Marketbasket of Food Hazards: Critical Gaps in Government Protection," Public Voice has advocated increased mandatory federal monitoring for fish safety as a means of reducing toxic contamination of fish and shellfish. We believe these foods present unnecessary, and too frequently, harmful risks to unsuspecting consumers.

Since that time, we have organized a nation-wide coalition of 35 consumer, health, and environmental groups calling for a comprehensive mandatory federal seafood inspection program. The list of these groups is included in my written remarks submitted to the Subcommittee.

Mr. Chairman, we applaud your concern about the current programs monitoring seafood safety and for convening today's hearing. We further commend you, Mr. Chairman, for taking the initiative in filing legislation, H.R.2511, calling for the establishment of a mandatory, comprehensive federal seafood inspection program. This bill, which addresses many of the concerns Public Voice has expressed about the current lack of protections for seafood consumers, will be important as the basis for discussions as Congress moves ahead on the issue of seafood safety.

The Surgeon General and the National Academy of Sciences have warned that the American diet is too high in fat, increasing the risk of heart disease, stroke, and certain cancers. These reports build on previous recommendations from the American Heart Association, American Cancer Society, and the National Institutes of Health. Even the US Department of Agriculture and the Department of Health and Human Services issued Dietary Guidelines for Americans in 1980 that call for diets lower in fat.

Americans have heeded this advice and turned increasingly to fish and shellfish for a low-fat alternative source of protein in their diets. Annual consumption of seafood in the United States increased by over 20% between 1980-1987 and is now well over 3 billion pounds.

Yet the sad irony of this healthful promise to consumers is that **seafood is the only flesh food in this country not subject to a comprehensive, mandatory federal inspection program.**

Recently, questions about the safety of seafood have been receiving increasing attention. In January, a special committee of the National Academy of Sciences Food and Nutrition Board began a two-year investigation into the health effects on the consumer from microbial and chemical contamination of fish.

And last year, public concern over fish safety showed up in the marketplace when, after a steady eight-year increase, seafood consumption went down by two percent. The change in public attitudes toward fish are documented in the results of a recently-released Harris public opinion poll conducted in November 1988 for Prevention Magazine. While the number of people buying low-fat or low-cholesterol foods rose nine percentage points from the year before, individuals reporting they try to eat fish twice a week dropped six percentage points since 1987.

The Risks of Acute Illness from Seafood

Seafood has certain characteristics which increase its potential to endanger human health. The risk of acute illness from bacteria and parasites is greater in fish and shellfish, which, unlike most meat and poultry, is generally harvested from uncontrolled environments. The waters from which fish are taken may be polluted with sewage, industrial chemicals, or pesticides.

In addition, certain types of seafood, such as shellfish, actually concentrate contaminants in their tissue. Even when refrigerated, fish and shellfish usually deteriorate quickly. And some seafood is commonly eaten raw.

It is estimated that thousands of Americans become ill each year from eating contaminated fish and shellfish. (See Chart A for a list detailing the most prominent microbiological hazards.) Disease-causing agents, like ciguatoxin and vibrio cholera bacteria, cause symptoms such as nausea,diarrhea, vomiting, fever and abdominal cramps, among other effects.

A summary of foodborne disease surveillance from the Centers for Disease Control (CDC) covering the 12-year period 1973-1984 reported 2,998 foodborne outbreaks of disease with known sources. According to the CDC figures, the total number of reported outbreaks traced to fish and shellfish actually exceeded the total reported outbreaks traced to beef and poultry combined. Seafood accounted for nearly 10% of the outbreaks, beef represented nearly 5%, and poultry 3.8% of the total outbreaks with a known source.

This figure takes on added significance because we eat more than four times as much beef and three times as much poultry as we do seafood.

When examined together with USDA consumption data for each of these food groups for the same period, the data shows that the relative risk of illness outbreaks for seafood compared to other meats is very high. **In fact, the risk of an food poisoning outbreak from eating seafood is actually 10.4 times greater from seafood than it is for beef, 6.9 times greater than for poultry, and 5.8 times greater than for pork.** (See Chart B.)

Quantifying the precise extent of illnesses proves impossible, however, as no effective nationwide system for collecting foodborne illness statistics exists. Underreporting in the case of fish and shellfish-related incidents is further compounded by the fact that many of the illnesses are short-lived gastrointestinal problems resembling a bout with the flu that may never come to the attention of health officials. CDC estimates that the outbreaks they document represent only between 1 percent and 5 percent of the actual number of outbreaks.

Frequently, representatives of government and industry say that 40 percent of reported seafood illnesses come from 9 states. This in large part can be explained by our poor reporting system. The quality of the data on foodborne illness depends on the priority given to foodborne disease surveillance by state and local health departments. Many states simply do not have the resources to monitor disease outbreaks. It is not surprising, for example, that New York State has one of the nation's best illness data collection systems and reports a large number of illnesses. But one would have to expect that its neighboring states would have similar illness rates proportional to their populations.

At FDA's December 16, 1988, "National Meeting on Cooked/Processed Seafood", Dr. John E. Kvenberg of FDA's Division of Microbiology presented disturbing results of FDA's 1988 microbial testing of processed seafood. Because processed seafood will usually not be cooked again before it's eaten, the presence of pathogens causes special concern. 14.4 percent of the 369 domestic samples of processed seafood were rated "Class 3"--enough pathogens were present to enable FDA to take official action, (e.g., a recall.) Crabmeat was contaminated frequently; 28.8 percent of the 165 samples were rated Class 3; 10.2 percent of the domestic 118 cooked shrimp samples also were actionable. Overall, the imports fared slightly better with 11.1 percent of the samples falling in the Class 3 category. The types of pathogens found included Listeria monocytogenes, vibrio cholera and E. coli. (See Chart C).

At the same FDA meeting, Richard Ronk, Acting Director of FDA's Center for Food Safety and Applied Nutrition explained that certain seafood companies do not follow good manufacturing practices, which exacerbates contamination problems. He said:

> This problem of microbial contamination must be brought under control. It is widely recognized that microorganisms readily adapt to changing environments...It is well documented that certain segments of the seafood industry are not conforming to current good manufacturing practices in handling their products. Cross-contamination of raw and processed products and improper storage temperatures are examples of the problems mentioned today which need to be addressed by the seafood industry. (Source: Prepared; text of Mr. Ronk's Oral Remarks, National Seafood meeting, December 16, 1988, Washington, DC).

Also at the National Seafood Meeting, Ron McKay, Assistant Administrator, Food and Dairy Division of Oregon's Department of Agriculture, described how his department's investigation in 1987 of 17 Oregon seafood processing plants showed that even in this modern age, seafood plants are still using horse and buggy technology that threatens the public's health. Mr. McKay gave examples with graphic slides of unhealthful manufacturing practices. Unfortunately, these industry practices are not unique to these locations. Some included:

--trash dumpsters without covers located outside a plant on its landing area. Seagulls were constantly attracted to the garbage. Their excrement littered the area on which seafood was delivered in open crates.

--wooden crates and totes which cannot be properly sanitized were used without plastic liners to hold raw and then finished cooked product.

--workers entering a plant walked through raw seafood juices before entering processing area and the firm did not provide a foot bath to cleanse their shoes.

The Oregon Agriculture Department made recommendations to these plants for sanitation improvements based on the HACCP approach.

Contamination of Seafood from Polluted Waterways

Pesticides and other chemical compounds which are present in waterways because of industrial and municipal dumping, agricultural run-off, and application of pesticides to marshes and shorelines pose a very real hazard to public health.

These chemical residues resist degradation, are incorporated into phytoplankton which is the first link in the food chain, and become concentrated in the tissues of fish and shellfish consumed by humans. Many of these residues present long term health risks to consumers. Some have been linked to cancer and other adverse health effects.

Even the limited data available on chemical contamination of fish demonstrates that toxins are commonplace in the seafood we eat. **Of all the domestic food samples collected and analyzed by FDA between 1979 and 1985, including vegetables and dairy products, fish had the highest percent of samples containing illegal residues, 5.2 percent**, whereas the market basket average was 2.9

percent. (Source: U.S. General Accounting Office, "Pesticides: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues", October 1986 at 27. According to the report, .7 percent of fruits and fruit products contained illegal residues and 3.7 percent of leafy and other vegetables were similarly contaminated.)

In 1987, FDA tested only 711 samples (total for both domestic and imported) for pesticide residues. In those samples, the agency found that 73 percent of the domestic seafood samples and 22 percent of the imported ones had pesticide residues.

The metals most frequently associated with residues in fish and shellfish are mercury, lead, cadmium and arsenic. Of these, mercury has probably received the most public attention because elevated levels of mercury residues were discovered in many fish in the early 1970's when mercury was widely used in pesticides. Today, the primary use for mercury is the manufacture of batteries, paints and industrial instruments. Most mercury accumulated in fish tissues is in the form of methyl mercury, which is readily absorbed by the intestine in man and is the most toxic form of mercury. Large fish such as tuna, shark, salmon, and king mackerel usually have the highest mercury levels. In humans, excess levels lead to loss of appetite, birth defects, central nervous system damage and kidney damage.

Another group of contaminants, the chlorinated hydrocarbons, such as polychlorinated biphenyls (PCB's) DDT, and Dioxin, are the result of industrial pollution and pesticide run-off. These chemicals contaminate many fresh, brackish and coastal waters.

PCB's are actually a group of more than 200 similar chemical compounds. From the 1930's to the mid-1970's, they were extensively used in industry as insulating fluids and coolants because they are extremely resistant to degradation. In 1977, manufacture of PCB's was banned in the U.S. because of concerns about long-range chronic health effects. PCB's are widespread in the environment and are frequently present in river and marine sediments as well as in the fatty tissues of fish.

State sportfishing advisories also give some indication for toxic hazards in fish. New York, for example, has closed some waterways to commercial fishing and has issued health advisories against sportfishing in areas because of chemical contamination. **A New York State Department of Health fishing advisory recommends eating no more than one meal per week of half a pound of fish taken from any water in the state.** The state also in April 1986 banned commercial fishing for striped bass in all New York waters. This ban was due to the fact that the DEC sampled 444 striped bass during the 1985 season, and almost all were contaminated with more than 2 ppm of PCB's, the FDA tolerance. A 1988 investigation by EPA into the public health impact of consumption of seafood from Quincy Bay, Massachusetts (known as the "flounder capital" of the world) showed that seafood can pose a serious risk of cancer. The risk estimates for the seafood were significantly higher than those estimated for consumption of other foods suspected to pose cancer risk (i.e.: with diet soda saccharin, with peanut butter aflatoxin). In particular, EPA found that "the estimated incremental risk (of cancer over a lifetime) (plausible upper bound) for the hypothetical Maximally Exposed Individual eating a mixed diet of Quincy seafood is about 50-100 times higher than the estimates for any of the other typical eating and drinking activities shown on the table. (See Chart D). The estimated risk (plausible upper bound) for just consumption of Quincy Bay winter flounder is about 10 times higher than the estimated for other typical eating and drinking activities." The other activities for comparisons included drinking milk, water, diet soda and eating peanut butter. (See Chart E). (Source: "Analysis of Risks from Consumption of Quincy Bay Fish and Shellfish," Prepared for U.S. EPA, Region I, May 1988 at 50-52).

Governmental Surveillance Inadequate

Given the serious potential health risks involved, it should be of deep concern to all of us that seafood gets hit-or-miss inspection at best under an inadequate patchwork of federal and state programs that address limited aspects of fish harvesting and processing. Federal seafood safety programs are fragmented, too often uncoordinated, and standards are often voluntary, absent entirely, or weakly monitored. State activities and budgets vary widely and do not compensate for federal weakness.

A 1986 report prepared for the National Marine Fisheries Service (NMFS), "Preliminary Analysis of a National Seafood Inspection Program" (Cooperative Agreement No. NA85AA-H-SK147) (hereinafter cited as NMFS Analysis) concluded that:

"**...present federal government efforts for ensuring the safety of U. S. seafood are minimal.** The FDA, which has authority for inspection of seafood in interstate commerce, carries out only limited surveillance inspection for most seafood and operates a National Shellfish Sanitation Program and a Canned Salmon Control Plan which are voluntary, cooperative programs. The voluntary inspection program of NMFS currently applies to only six percent of U.S. processing plants and an estimated 12 percent of seafood eaten by U. S. consumers." (at 2-2, highlighting added).

National Marine Fisheries Service

The National Marine Fisheries Service, (NMFS) a division of the Department of Commerce, operates a voluntary inspection and grading program, paid for by the corporate users. It is designed as a marketing tool to promote the marketing of fish products for the benefit of the domestic fisheries industry. Its grading service emphasizes uniformity of size, flavor, and freedom from blemishes. It is not a public health program. Despite the fact that per capita fish consumption has been rising steadily, the NMFS inspection service has been sharply decreasing. In 1987, NMFS' program covered about 11 percent of seafood consumed, down from about 18 percent in 1983.

Food and Drug Administration

The Food and Drug Administration (FDA) has authority to inspect seafood in interstate commerce as part of its general authority over all foods crossing state lines. Its surveillance is woefully scanty. For example, in 1987, FDA inspected 789 of the manufacturing and repacking plants engaged in the processing of fish and/or seafood, amounting to only 25 percent of the total

number of plants in operation that given year.

FDA's monitoring of chemical and pesticide contamination is also seriously inadequate. FDA, in cooperation with the Environmental Protection Agency (EPA), has established very few limits for toxins in seafood. **There is only one tolerance (compound limit) and only thirteen informal action levels for hazardous substances in fish (See Chart F), despite the fact that hundreds of chemicals may pose potential health threats.**

These weak standards do not give the public much protection. Only a tolerance is binding on the courts, the regulated industry and the agency. The action levels do not have the force of law. Thus, FDA is not required to initiate an enforcement action if an action level is exceeded.

In addition to lack of standards for chemical hazards, FDA tests only a minute percentage of fish for dangerous levels of residues. For example, **in 1987 the agency analyzed only 996 domestic and 628 imported seafood samples for pesticide and chemical residues. Meanwhile, Americans consumed over 3 billion pounds of fish in that same year!**

In stark contrast, the U.S. Department of Agriculture operates a more effective, statistically valid program for sampling meat for drug, pesticides and environmental contaminants. USDA's present routine monitoring provides a 95 percent probability of detecting a tested-for residue problem if it occurs in one percent of a slaughter population. In 1989, USDA expects to routinely monitor 44,000 samples. It will check approximately 24,800 biased samples for the surveillance part of the program. (Source: Speech of Dr. Lester M. Crawford, Administrator of the Food Safety and Inspection Service, USDA, before the Board of Inquiry of the European Parliament, Strausbourg, France, December 12, 1988.)

One example of the weakness of FDA's sampling program was revealed at a hearing held in California on February 10, 1986, by the House of Representative's Health and Environment Subcommittee on DDT pollution of Santa Monica Bay. The Montrose Chemical Company, which produced half the world's DDT before it was banned, discharged 400 to 600 pounds of DDT daily into the Santa Monica Bay for 26 years until 1972.

Several issues raised at the hearing suggest that the public may be exposed to dangerous levels of chemical residues from fish caught in southern California. The most striking evidence presented at the hearing were the results of a pilot study conducted by scientists in the L.A. Weekly, February 21, 1986. The researchers went to the markets throughout Los Angeles and bought over 150 fish caught locally. The researchers found that the fish had the highest overall concentrations of DDT of any seafood in the nation, and that several species such as ocean perch, white croaker, barracuda and mackerel had concentrations of both DDT and PCB's up to 50 times the national average, comparable to levels from areas that California health officials had closed due to the potential danger to public health.

FDA's own sampling for DDT residues in Los Angeles fish was minimal at best. At the hearing, David Steinman from Loma Linda

University testified that in 1984-85, 57 million pounds of fish were landed in Los Angeles alone, but FDA had sampled only 30 fish through midyear 1985. FDA's enforcement activity in this area appears to have been grossly insufficient to guard against dangerously contaminated fish entering the marketplace.

National Shellfish Sanitation Program

Oversight of shellfish harvesting is done only through a voluntary program of states that agree to follow guidelines established by the Food and Drug Administration as part of the National Shellfish Sanitation Program (NSSP). Because shellfish filter and concentrate pathogenic microorganisms and toxic substances, and particularly because shellfish are eaten raw, they present a strong health risk. Under the NSSP, FDA reviews each state's program to determine whether it should be endorsed or not. FDA also publishes a list of approved interstate shellfish shippers.

The FDA's 1988 annual report on the status of state shellfish sanitation programs cited nine states out of 23 that participate for "major program deficiencies of public health significance." **Those states produced 54 percent of the U. S. shellfish harvest.** (See Chart G). Six of the states remained in "nonconformity" for the second consecutive year. Inadequately completed sanitary surveys of shellfish growing waters was a common cause for noncompliance.

The FDA report stated that "there is a growing concern that the improvements being made may be overshadowed or even negated by program deficiencies in the patrol and depuration program areas...." It also indicated the situation may worsen because "many states now judged to be marginally in program conformity will slip into nonconformity because program funding is not keeping abreast of program needs...."

A 1984 report by the General Accounting Office (GAO) entitled "Problems in Protecting Consumers from Illegally Harvested Shellfish" concluded that NSSP does not achieve its goal of ensuring that shellfish harvested in the United States is safe for human consumption. Among the weaknesses highlighted by GAO was that the voluntary nature of the program hinders it effectiveness. FDA's only available sanction is to withdraw endorsement of a state program, and this sanction has never been used and rarely even threatened.

Mandatory Federal Inspection Needed

American consumers need protection from the health risks associated with eating fish and shellfish and they need it now. Public Voice, along with a national coalition of 35 consumer, environmental and health organizations, has called for a comprehensive, well-integrated federal seafood inspection program.

We were very pleased to see generally included in H.R.2511 so many of the elements we have called for in a mandatory federal seafood inspection program, including:

-Federal standards for sanitary conditions and good manufacturing practices on fishing vessels;

-Requirement of good manufacturing practices and authorization of spot checks of fish processing facilities;

-Establishment of federal microbiological and chemical standards with meaningful residue sampling program;

-Improved standards and inspection of imports;

-Establishment of a traceback and recordkeeping system for fish and their source of origin;

-Increased enforcement activities for federal officials;

-Appropriate funding for development of needed test methodology for toxins.

In addition, we suggest legislation also include the following elements:

-The addition of civil sanctions as an enforcement option against those who violate the law;

-Provision for certification and regular unannounced inspection of fishing vessels;

-Establishment of a program to address economic fraud (e.g., deceptive labeling of products, glazing).

Finally, we believe the U.S. Department of Agriculture should act as the lead agency with monitoring of chemical contamination retained by the Food and Drug Administration.

USDA's Food Safety and Inspection Service is the best agency to carry out the program because its major mission is to oversee problems relating to the American food supply, and FSIS' main directive is to protect the public health rather than to promote marketing. FSIS now administers meat and poultry inspection and has the greatest experience with comprehensive flesh food inspection. It also has the largest research institution, the Agricultural Research Service. Further, its budget scope and resources are compatible with the size of funding that would be added by seafood inspection.

Mr. Chairman, members of the Subcommittee, many Americans are still unaware of the potential dangers of seafood and they are turning to fish as one way of eating a healthier diet. Unless legislation establishing a comprehensive, mandatory seafood inspection program is enacted and signed in this Congress, those same health conscious consumers will be putting themselves at increasing risk of serious illness, even death.

On behalf of Public Voice and the Coalition for Mandatory Federal Fish Inspection, I congratulate you, Mr. Chairman, for demonstrating your concern for ensuring the safety of the nation's seafood supply and for helping move the discussion of this critical issue forward with the legislation you have filed. We offer whatever assistance we can provide in closing this serious gap in the federal food monitoring system.

Chart A

Microbiological and Parasitic Hazards of Fish and Shellfish

Fish Source	Toxins and Parasites	Disease Threat to Consumers	Symptoms
Most outbreaks caused by improperly preserved canned foods	C. botulinum	Botulism	Double vision, weakness, difficulty breathing; can cause paralysis by acting on the nervous system
Primarily bottom-dwelling shore fish caught near reefs; most commonly barracuda, red snapper, amberjack and grouper	Ciguatoxin	Ciguatera Fish Poisoning	Nausea, cramps, diarrhea, numbness of lips and tongue, reversal of hot and cold sensation, pain in extremities
Primarily tuna, mackerel, bonito and skipjack	Scombrotoxin	Scombroid Fish Poisoning	Flushing, headache, dizziness, burning of mouth and throat, bronchospasm, abdominal cramps, nausea, diarrhea
Pufferfish	Tetrodoxin	Fish Poisoning	Numbness, loss of perception, floating sensation
Mostly associated with eating raw or undercooked fish, such as sushi and sashimi	Anisakid-nematode	Anisakiadis	Stomach pains, nausea and vomiting; may penetrate stomach wall
Mollusks,[a/] particularly those harvested from waters contaminated with sewage	Vibrio cholerae-01 bacteria	Cholera	Diarrhea; if case severe, can lead to dehydration and death

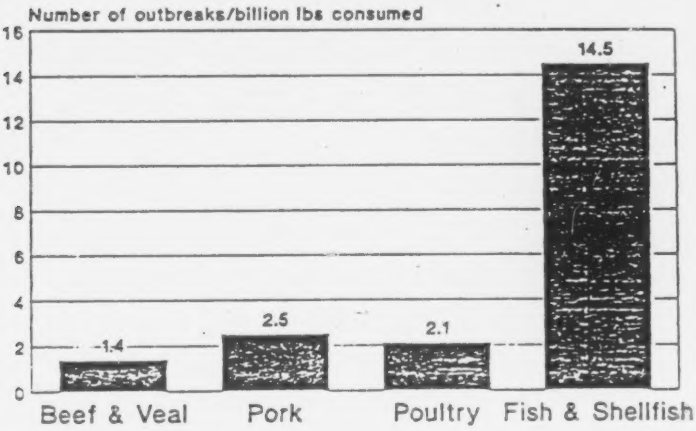
Chart A: (continued...)

Fish Source	Toxins and Parasites	Disease Threat to Consumers	Symptoms
Mollusks, particularly those harvested in summer months (bacteria multiplies more rapidly in warm water)	Vibrio cholerae non-01 bacteria	Gastroenteritis	Diarrhea, vomiting, fever, abdominal cramps
Mollusks (particularly if eaten raw)	Vibrio parahaemolyticus bacteria	Gastroenteritis	Abdominal pain, diarrhea, nausea, headache, fever
Mollusks	Vibrio vulnificus-bacteria	Septicemia	Abrupt onset of chills, fever and/or prostration (usually only people with liver disease are at risk)
Mollusks	Salmonella bacteria	Salmonellosis	Nausea, fever, headache, abdominal cramps, diarrhea
Mollusks (particularly if eaten raw)	Hepatitis-A virus	Hepatitus	Appetite loss, vomiting, diarrhea, and abdominal pain
Mollusks	Norwalk virus	Gastroenteritis	Nausea, vomiting, diarrhea, and abdominal pain
Shellfish	Gonyaulax	Paralytic shellfish poisoning	Tingling, numbness, burning sensation in the lips, tongue and face, muscular weakness, respiratory paralysis and gradual paralysis of extremities
Shellfish	Ptychodiscus	Neurtoxic shellfish poisoning	Tingling of extremities, reversal of hot and cold sensation, vomiting, diarrhea

Note a: Mollusks are a phylum of invertebrate animals including oysters, clams, mussels and snails.

CHART B

Number of outbreaks/billion lbs consumed
(1973-1984)



Source:Reported outbreaks from CDC and
food group consumption data from USDA

CHART C

1988 FDA's Processed Seafood Analysis

	Number of Samples	Contaminated at level that could result in FDA Action (such as recall)
Domestic		
Crabmeat	165	28.8%
Cooked Shrimp	118	10.2%
Surimi	72	1.4%
Crawfish	10	20%
Nova Salmon	4	25%
	369	14.4%
Imported		
Crabmeat	94	16%
Cooked Shrimp	48	8.3%
Surimi	112	1.8%
Crawfish	10	50%
Lobster	6	16.7%
	270	11.1%

(Source: Kvenberg Oral Presentation, National Seafood Meeting, Dec. 16, 1988, Washington, DC).

CHART D

Upper Bound Estimated Life Time Cancer Risks From Consumption of Quincy Bay Seafood

	Maximally Exposed Individual		Typical Exposed Individual	
	Mixed Diet	Flounder	Mixed Diet	Mixed Diet
Clams	$2.1x10^{-4}$ (1%)	-	-	-
Flounder	$3.2x10^{-3}$ (14%)	$4.7x10^{-3}$ (100%)	$2.8x10^{-5}$ (33%)	$2.8x10^{-5}$ (2.2%)
Lobster Meat	$8.0x10^{-4}$ (3.4%)	-	$5.6x10^{-5}$ (67%)	$4.5x10^{-5}$ (3.5%)
Tomalley	$1.9x10^{-2}$ (82.6%)	-	-	$1.2x10^{-3}$ (92.3%)
Total Risk	$2.3x10^{-2}$	$4.7x10^{-3}$	$8.4x10^{-5}$	$1.3x10^{-3}$

Source: Analysis of Risks from Consumption of Quincy Bay Fish and Shellfish, Prepared for United States Environmental Protection Agency Region I, May 1988.

CHART E

Comparison of Estimated Lifetime Cancer Risks (Plausible Upper Limit)

Lifetime Cancer Risks From Eating and Drinking Activities	Estimated Lifetime Risks(a)
-Maximally Exposed Individual - mixed diet of Quincy Bay seafood	1.5 to 2.3 x 10^{-2}
-Maximally Exposed Individual - diet of Quincy Bay winter flounder	1.7 to 4.7 x 10^{-3}
-Typical Quincy area resident - mixed diet of Quincy Bay seafood, including lobster tomalley	9.2 x 10^{-4} to 1.3 x 10^{-3}
-Four Tablespoons peanut butter per day	5.6 x 10^{-4}
-One 12 1/2 ounce diet drink per day (6)	7.0 x 10^{-4}
-Average saccharin consumption in the United States	1.4 x 10^{-4}
-One pint milk per day (b)	1.4 x 10^{-4}
-Typical Quincy area resident - mixed diet of Quincy Bay seafood without lobster tomalley	4.7 x 10^{-5} to 8.4 x 10^{-5}
-Miami or New Orleans drinking water	7.0 x 10^{-5}
-1/2 lb. charcoal broiled steak per	2.1 x 10^{-7}

(cancer risk only; heart attack and other risks additional)

a) Except for Quincy Bay seafood consumption estimates for subpopulations, all other estimates are averaged over the whole population of the United States, assuming a 70 year lifetime.

b) Based on human data for aflatoxin carcinogenicity. Note that it is assumed that the measured aflatoxins are aflatoxin B, the most potent. If some corresponds to other aflatoxins, these estimated risks should be reduced.

Source: Analysis of Risks from Consumption of Quincy Bay Fish and Shellfish, Prepared for United States Environmental Protection Agency Region I, May 1988.

CHART F

FDA Action Levels for Poisonous or Delterious Chemical Substances in Seafood (Informal Standard)

Chemical	Seafood	Action Level (parts per million)
Aldrin	Fish & Shellfish	.3
Dieldrin	Fish & Shellfish	.3
Chlordane	Fish	.3
DDT, DDE and TDE (in adding the amounts of DDT, DDE, and TDE any of the three found below .2 ppm for fish is not counted)	Fish	5.0
Endrin	Fish & Shellfish	.3
Heptachlor	Fish & Shellfish	.3
Heptachlor Epoxide	Fish & Shellfish	.3
Kepone	Crabmeat, Fish & Shellfish	.4 .3
Mercury	Fish, Shellfish and Crustaceans	1.0
Mirex	Fish	.1
Toxaphene	Fish	5.0

FDA Tolerance Level (Formally Standard)

Chemical	Seafood	(Parts per million)
Polychlorinated Biphenyls (PBC's)	Fish	2.0

Chart G

Voluntary National Shellfish Sanitation Program State Conformity With Guidelines Set By FDA – 1987

States	Commercial Landing (1,000 Lbs.)	Percent of US Total Landings	FDA Evaluation of Conformance of State Shellfish Sanitation Program with NSSP*
Alabama	19,596	2%	C
Alaska	156,607	13%	C
Arizona	NA	NA	NA
Arkansas	23	<1	NA
California	108,384	9%	NC
Colorado	NA	NA	NA
Connecticut	3,099	<1	NC
Delaware	4,290	<1	C
Florida	57,437	5%	C
Georgia	13,882	1%	C
Hawaii	1,094	<1	NA
Idaho	NA	NA	NA
Illinois	NA	NA	NA
Indiana	NA	NA	NA
Iowa	NA	NA	NA
Kansas	NA	NA	NA
Kentucky	90	<1	NA
Louisiana	189,350	16%	NC
Maine	46,651	4%	NC
Maryland	70,455	6%	C
Massachusetts	52,417	4%	NC
Michigan	NA	NA	NA
Minnesota	NA	NA	NA
Mississippi	14,397	1%	C
Missouri	NA	NA	NA
Montana	NA	NA	NA
Nebraska	NA	NA	NA
Nevada	NA	NA	NA
New Hampshire	1,475	<1	C
New Jersey	81,815	7%	NC
New Mexico	NA	NA	NA
New York	15,743	1%	NC
North Carolina	41,786	4%	C
North Dakota	NA	NA	NA
Ohio	NA	NA	NA
Oklahoma	1,069	<1	NA
Oregon	51,542	4%	NC
Pennsylvania	NA	NA	C
Rhode Island	28,053	2%	C

Voluntary National Shellfish Sanitation Program
State Conformity With Guidelines Set By FDA - 1987

States	Commercial Landing (1,000 Lbs.)	Percent of US Total Landings	FDA Evaluation of Conformance of State Shellfish Sanitation Program with NSSP*
South Carolina	11,040	1%	C
South Dakota	NA	NA	NA
Tennessee	2,054	<1	NA
Texas	106,369	9%	NC
Utah	NA	NA	NA
Vermont	NA	NA	NA
Virginia	69,561	6%	C
Washington	39,286	3%	C
West Virginia	NA	NA	NA
Wisconsin	NA	NA	NA
Wyoming	NA	NA	NA

C = Conforming

NA = Not Applicable

NC = Non-Conforming with National Shellfish Sanitation Program
Voluntary Guidelines Set by FDA

* Source = FDA Shellfish Sanitation Branch, "Report to the Interstate Shellfish Sanitation Conference: Status of State Shellfish Sanitation Program, 1987."

COALITION FOR MANDATORY FEDERAL FISH INSPECTION

Public Voice for Food and Health Policy
Alaska Public Interest Research Group
American Council on Consumer Awareness
Americans for Democratic Action/Consumer Affairs Committee
Americans for Safe Food
Arizona Consumers Council
Consumer Education and Protection Association of Kansans, Inc.
Center for Science in the Public Interest
Concern, Inc.
Concerned Consumers League
Consumer Action
Consumer Federation of America
Detroit Consumer Affairs Department
Earth Keep
Empire State Consumer Association
Environmental Action
Food and Water
Friends of the Earth
Gray Panthers of San Francisco
Harlem Consumer Education Council, Inc.
Human Environment Center
Idaho Consumer Affairs, Inc.
Iowa Consumers League
Michigan Citizens Lobby
National African-American Consumer Organization
National Consumers League
Natural Resources Defense Council
NY City Department of Consumer Affairs
Oceanic Society
Physicians Comm. for Responsible Medicine
Public Citizen Congress Watch
Rhode Island Public Interest Research Group
Vermont Public Interest Research Group
Wisconsin Consumers League
Wisconsin Family Farm Defense Fund

as of 5/18/89

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STATEMENT
OF
LEE J. WEDDIG
EXECUTIVE VICE PRESIDENT
NATIONAL FISHERIES INSTITUTE
TO THE
SUBCOMMITTEE ON FISHERIES AND WILDLIFE
CONSERVATION AND THE
ENVIRONMENT
ON
H.R. 2511

The National Fisheries Institute is the largest seafood industry trade association representing over 1,000 member companies involved in all aspects of the seafood industry.

STATEMENT
OF
LEE J. WEDDIG
EXECUTIVE VICE PRESIDENT
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TO THE
SUBCOMMITTEE ON FISHERIES AND WILDLIFE CONSERVATION AND THE ENVIRONMENT

Twenty-two years ago, the late Senator Philip Hart spoke at the annual convention of the National Fisheries Institute and outlined his belief that there was need for a better seafood inspection program. Senator Hart subsequently introduced legislation which was investigated in hearings, actually passed the Senate, but did not make it into law.

At the time, the seafood industry was struggling. The Soviet and other foreign fishing fleets were decimating our resources; the Catholic Church had just changed its dietary rules, allowing meat to be eaten on Fridays; and a well publicized incident involving botulism in smoked Michigan whitefish had scared consumers.

A lot has changed since 1967. The Magnuson Fisheries Conservation and Management Act provided means in 1976 to control foreign and domestic fishing pressure on the resources. Fish has become an everyday, not a Friday, food, and the previously unknown potential of botulism in smoked fish is safeguarded by processing and handling procedures.

The most dramatic change since 1967 has been the growth of the fish and shellfish in the American diet. In 1967, per capita consumption was 10.6 pounds edible weight. Last year it was 15 pounds, an increase of more than 46 percent. Even more significant is the growth of fresh and frozen products, as opposed to canned. Here the increase was from 5.8 to 9.6 pounds, a 65 percent increase.

For most consumers, fish and shellfish is no longer an occasional food, or special treat. Seafood is a full fledged every day choice of consumers, along with beef, pork and poultry. The public realizes that fish provide excellent nutrition...low fat, low cholesterol and easily digested proteins.

These characteristics, together with the unique tastes and flavors of properly prepared seafood, and the desire for variety, strongly suggest that seafood consumption will continue to grow.

Such growth is good for the country. Health experts advise that heart disease can be alleviated by dietary changes which include more fish. Improvements in public health have direct benefits for the country. Certainly, quality of life is improved with variety; and the nation's economy benefits from a vibrant primary industry which creates income and jobs from renewable natural resources.

These benefits will accrue in the future only if consumers have full confidence in the safety, wholesomeness, and integrity of fish and seafood products. The National Fisheries Institute believes this confidence is in jeopardy and will be maintained and strengthened only through an improved regulatory system which includes mandatory inspection.

It is this belief which prompts our commendation of Chairman Studds and Congressman Young for introducing H.R. 2511. Once again you have demonstrated leadership in coming to grips with a difficult problem facing the fisheries.

Establishing a new regulatory system which embodies mandatory inspection is particularly challenging because of the vast diversity of the seafood industry. But the task is begun with the introduction of H.R. 2511 and we thank you for it.

Bringing the issue of seafood inspection to a successful conclusion is important to the country since the impact on the economy of the fish and seafood industry is far more extensive than most people realize. A recent study conducted by the National Fisheries Education and Research Foundation shows that direct, indirect and induced economic impacts attributable to fish and seafood exceed $80 billion annually. More than one million full-time equivalent jobs are generated. These are big numbers and reflect the myriad pathways on which fish products move from the dock to the dinner table. The study shows that consumers pay about $30 billion annually for fish and seafood with about two-thirds being consumed in restaurants and other food service establishments.

While many of the economic impacts occur in the metropolitan areas, since that is where the value of distribution and service is realized, the primary economic impacts are generated in rural areas where jobs are needed.

The seafood industry is very trade dependent, for both our markets and supplies. More than 3 billion pounds of product worth $5.5 billion were imported last year. This was slightly greater than imports of meat and poultry in volume, but substantially higher in value. As for exports, fishery products soared in 1988, exceeding one billion pounds and $2.1 billion, making the U.S. the world's largest fish exporter. The value of fish exports exceeds that of meat and poultry.

It is evident that seafood is a major component of our nation's food supply-- a component important enough to the consumer and the economy that our ability to maintain the confidence of consumers here and overseas must be protected for the common good.

Contrary to popular opinion, the fish and seafood industry is not without regulation. We are subject to the Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act. These laws are enforced by the Food and Drug Administration. Enforcement includes plant and product inspections and port-of-entry inspections for imports. The extent of this enforcement activity varies, but it does exist and has been documented in such reports as the General Accounting Office study of August, 1988 on Seafood Safety and the responses of the FDA to questions raised by the Chairman of the House Subcommittee on Oversight and Investigations of the Energy and Commerce Committee.

Various states also enforce their laws relating to food safety. In respect to molluscan shellfish, the coastal state governments, in coordination with the FDA, operate the National Shellfish Sanitation Program. Finally, the U.S. Department of Commerce provides a for fee voluntary inspection and grading service under the Agricultural Marketing Act of 1946.

The actions of overseas governments also have a bearing on seafood safety. Such major supplier nations as Canada, Norway and Iceland, among others, have seafood inspection programs specifically designed for fish and seafood.

The problem is not that there is no inspection system, but rather that the present system is inconsistent and incomplete and thus does not provide the level of assurance demanded by the public. This demand is strong and it's becoming evidenced in direct fashion. Certain consumers are reducing or avoiding fish consumption. Recent surveys by the Food Marketing Institute showed 15 percent of consumers are avoiding fish for safety reasons. A large part of the current demand that more be done to assure the safety of fish stems from concern over the marine environment which has suffered from decades of toxic substance discharge, substandard sewage treatment, oceanic sludge dumping, pesticide run-off, and oil spills. While there is little evidence to show that present levels of toxic chemicals in fish have actually caused illness, there remains a nagging concern over the long-term impacts.

Examination of the data on actual illnesses and deaths attributable to seafood, and analysis of the data's meaning, do not show widespread problems. The GAO report and documentation by the National Marine Fisheries Service and the FDA attest to this. A larger study now in progress at the National Academy of Sciences can be expected to shed more light on the extent of real problems attributed to seafood as well as to offer recommendations on how these are to be corrected.

It does appear that the major sources of illness attributable to seafood are those caused by contaminated molluscan shellfish when eaten raw; by ciguatoxic reef fish, a problem confined primarily to our tropical island territories; and scombrotoxic fish, a problem unique to a certain class of fish in which histamine can build up if the product is mishandled.

It is important to note that the seafood products which make up virtually all of consumption exhibit an excellent record of safety. It is equally important to note that many of the actual cases are the result of natural environmental conditions, the ciguatoxic fish and some of the raw molluscan shellfish to be specific. Also, although many fish are caught recreationally, the impact of sports caught fish in the illness statistics is not known.

While the degree of risk of illness attributable to seafood can be, and is, debated, NFI believes that the regulatory system should be intensified in all areas in which any type of statistical evidence of illness exists. Certainly, a new regulatory scheme must specifically address the problems of ciguatoxin, scombrotoxin and the unique natural toxins, bacteria and viruses at times found in mollusks.

We do not wish to minimize or discount the problems currently affecting relatively small percentages of our products. However, our basic position is that a new system is needed to anticipate rather than react to problems. Such a proactive program is needed because of significant changes in occurring in our industry. Included are:

- Emergence of new species of fish on the market from new areas of the world. One of the attributes of the industry is the variety provided by new products, orange roughy, dory, hoki to name a few.
- Emergence of processing operations in developing nations. Many products are now processed, some into ready-to-eat form in such far away places as Taiwan, Thailand, the Philippines. The present system provides no means of checking the sanitary and other procedures in these locations other than at the U.S. port of entry.
- Emergence of aquaculture as a major source of products. Farm-raised fish is reported to be the fastest growing sector of agriculture in the U.S. It also is booming in other parts of the world. Farming fish involves the use of medications and feeds which should be monitored.
- New processing technology. One of the contributors to per capita consumption increases has been the surimi based family of products. This involves high tech food science; many additional innovations such as the mixing of fish and animal proteins can be expected. But new technology also opens the door to new potential problems.
- Growth in fully processed, ready-to-eat seafood. Social changes which provide less time for traditional home cooked meals and a growing shortage of labor for

food service operators are encouraging the development of more and more ready-to-eat, or heat-and-serve products. These provide value to the consumer. However, since they are eaten without further cooking, their preparation in a processing plant demands scrupulous attention to sanitation and avoidance of cross-contamination. Specific good manufacturing procedures must be developed and employed.

- Processing at sea. Many products are processed at sea, out of easy access by inspectors. A new system must address this type of operation.
- Recognition of new bacteria and viruses. It seems that scientists are learning rapidly about the pathogenicity of certain bacteria and virus. Listeria monocytogenes and vibrio vulnificus are two of the pathogens now under scrutiny. As more causative agents are discovered or better defined, procedures and regulations will have to change.
- Continued environmental concerns. The persistent use of the oceans as a convenient disposal site is a major concern. Fish in certain areas will absorb trace amounts of various industrial and agricultural toxic substances. The presence of such substances in fish is not of short term significance. However, many health professionals are concerned that long-term exposure to these chemicals, even in trace amounts, constitutes

> undue risk to consumers. This concern poses real difficulties for the commercial industry, in that constant attention to the issue is raised by environmental and other groups seeking the very important and necessary changes in water quality practices. Health authorities feel obliged to warn recreational anglers about the long term risks of heavy consumption of certain species caught in polluted waters. While commercial fishing is often prohibited in these waters, and the warnings have no relevance to commercial product, the widely publicized warnings are generalized and cause apprehension in the minds of consumers.

These concerns prompted the National Fisheries Institute in 1985 to revive legislative efforts to improve the seafood inspection system. Our decision came after extensive debate, since few in industry want to invite greater regulation.

Our Board, however, believed that the real problems, the perceived problems, concerns over economic violations of law fostered by rising demand, and the problems on the horizon could be addressed only by a strong governmental program. The decision was not accepted universally within the industry. Many plant operators feared the unknown and did not want to endorse a change in regulation without knowing what was being planned.

NFI's first action was to ask Congress to mandate the design of a seafood inspection system based on the Hazard Analysis Critical Control Point (HACCP) concept recommended by the

National Academy of Sciences. The design of this seafood surveillance program has been underway for the past two year. It includes the National Academy of Sciences study referenced earlier.

The industry is contributing considerable time and effort to see that this study is completed as soon as possible, with hundreds of industry professionals devoting thousands of days in government workshops and meetings. This work must be completed. We believe it will provide the integral mechanism for a new regulatory program. The HACCP concept is not new. It is already incorporated in the FDA's low-acid canned food regulations. Very simply, HACCP is a safety-quality assurance system that provides for monitoring of those steps in a processing operation which have the potential of causing hazards. A separate HACCP procedure must be established for each different processing operation, i.e., one for a cooked shrimp processor, another for breaded shrimp, and so on through the entire range of processes in the industry.

The procedure employed is to:

- Define the operational steps;
- Identify the hazards;
- Determine the preventive measures for each hazard;
- Identify monitoring procedures for the hazard preventive measure;
- Assign relative importance for the hazards;
- Define the critical control or monitoring points; and
- Identify the records necessary to assure compliance.

We believe that the HACCP systems should be mandated as the key regulatory tool of an improved inspection system. We also believe that the overall comprehensive seafood regulatory system should include the following elements:

- Certification of Plants. This would involve an initial inspection of facilities and procedures; in short, assurance that the facility has the capability of producing wholesome product. The facility requirements would have to be specific to the type of processing and species handled. Certification would involve a registry of plants.
- Surveillance of operations. This aspect would require HACCP procedures by the plant operator and inspection to verify plant adherence to these on an as needed basis by the designated authority. The intensity of this surveillance would vary according to the degree of risk involved in the process and the record of the operator.
- Surveillance of Imports. Foreign governments wishing to have products imported into the United States would be encouraged to establish regulatory programs which would provide assurance of compliance to U.S. regulations. The level of sophistication in these systems would be measured by site visits and port-of-entry monitoring.
- Increased molluscan growing water monitoring and enforcement. The current shellfish program provides

the base for improvements in this very important area. Additional research to improve the reliability of the system is needed as well as funding to the states for increased monitoring and enforcement.

- Toxic substance monitoring. While current levels of contamination due to industrial pollution have not had widespread impact on the safety of coastal and oceanic resources, there is a need for continual monitoring of the resources for toxic substance residues. This effort on both domestic and imported product would serve to trigger compliance efforts through the HACCP programs and port-of-entry inspections if and when the surveillance shows persistent presence of toxins at levels of concern.
- Economic violation enforcement. The inspection system should include monitoring for economic abuses. Under the present regulatory system, economic violations do not receive intensive enforcement efforts. Since certain economic violations can result in safety concerns, we believe there is need to provide increased enforcement capabilities in this area. Increased enforcement is necessary also to assure fair dealing and to overcome any lapse of consumers' confidence as to receiving what is being paid for.

In summary, we see an improved regulatory system combining a series of new or expanded inspection and self monitoring efforts.

The system would be developed and implemented consistent with the risk-based HACCP concept and would be mandatory.

This proposed system should be designed to meet unique concerns of seafood. It would be different than the carcass-by-carcass examinations of meat and poultry, and certainly different than regulatory systems for dairy products and other foods. Its establishment is a large task, one which will require a phase-in for both the industry and government.

The government agency chosen to establish such a system will face a very challenging task. The harvest and marketing of live lobsters is far different than the processing of Alaska pollock into imitation crab meat. Fish smoking requires a different code of practice than marketing fresh haddock fillets, and on and on. Government-to-government understandings must be reached with more than 80 foreign governments. The number of import shipments exceeds 160,000 annually at scores of ports of entry--all the way from northern Minnesota and Michigan to Nogales, Arizona, as well as the more readily expected seaports. There is need for rapid response. Perishable products cannot wait. And a single container of lobster tail, as an example, can have a value in excess of one half million dollars. Undue delays are very expensive. The plants are very often in remote locations and are often small and seasonal.

There are three federal agencies which could be given the seafood inspection task--the Food and Drug Administration; the Department of Commerce; and the Department of Agriculture. Each of these agencies offers strengths and each has some weaknesses.

The Food and Drug Administration already has much of the legal authority needed. It has impressive credentials and expertise in the fields of microbiology, virology, parasitology and so on. It already inspects foods at the ports of entry and administers the National Shellfish Sanitation program. It also works closely with state health agencies.

On the negative side, FDA's other responsibilities are expanding and it has had difficulty in obtaining funding to fulfill them. Its matrix type of organization may be inconsistent with a dedicated program. It seems to operate in a crisis mode and lacks an overseas capability in food inspection. In these circumstances, a dedicated large seafood program could create an imbalance with FDA's other functions.

The Department of Commerce has impressive fishery expertise in the National Marine Fisheries Service. It has a core group of inspectors, some laboratories and standard setting procedures. It has daily contact with the industry. It has some authority to enforce foreign and state fish laws and is the federal fishery resource management agency.

On the other hand, the Department of Commerce also has had trouble with funding for expanded responsibilities and obligations to protect species and manage fisheries. The Department's responsibilities and the Fisheries Conservation and Management Act are all consuming. Resource assessment needs are growing. Habitat protection is not keeping pace. At times we question the dedication of the top levels of the Department to its fisheries responsibilities. We would also question whether consumers would have confidence in the Department as a food safety authority.

The Department of Agriculture has over 80 year's experience in food safety. It has the managerial infrastructure in place to handle large scale programs. It has respected scientific capabilities and the confidence of consumers. It also has the lead federal role in aquaculture, which is a rapidly growing source of supply. USDA has established ties to overseas governments through its present inspection program and is heavily involved in export enhancement. A large-scale program would not be out of proportion to the rest of the agency.

Negatively, USDA lacks extensive experience with fish. A fish program might be overwhelmed by meat and poultry activities. The idea of continuous inspection may be so ingrained in the USDA that a HACCP program may not work. USDA has no tie to the management of wild stocks of fish.

The National Fisheries Institute in early discussions of the issue came to the conclusion that the most logical agency was the Department of Agriculture, with the assumption that the existing DOC inspection program would become a part of USDA. There are several reasons for this conclusion, but the most important ones were USDA's experience with large-scale operations in the field and its overseas capabilities.

In this statement we noted several times the need for ties to resource management. By this we mean the ability to prohibit commercial fishing in areas or for species which fail to pass muster with toxic substance residue tolerances. The concept is not new. Presently, molluscan shellfish safety is assured by monitoring and regulating shellfish growing waters. The same approach is used for some finfish at the state level. For example, New York restricts the commercial harvest of fish from areas contaminated with PCBs.

We believe that controlling harvests is an effective way of achieving compliance to environmental contaminant tolerances. Once fish are caught, it is usually economically prohibitive to separate fish in compliance from those with excess residues. Accordingly, when problems are identified, harvest restrictions should be imposed.

The question of financing a program must be addressed. It is our strong opinion that since appropriated funds are being used to provide the inspection system for meat and poultry, simple fairness dictates that appropriated funds be used for fish inspection. We compete with meat and poultry in the market. Presently, those packers who utilize the USDA voluntary inspection service operate at a disadvantage since they incur heavy costs not borne by their competitors.

The industry recognizes that the move to more intense regulation will not be simple or painless. But, the record shows that the U.S. fish and seafood industry has matured greatly since the time Senator Hart first broached the subject of inspection more than 20 years ago.

The very introduction of legislation in the past caused a reexamination of practices in the industry with resulting improvements in quality and wholesomeness. These improvements have contributed to the growth the industry has achieved. We believe that it's time to complete the work begun by the good Senator and to legislate a mandatory fish inspection program.

COMMENTS ON H.R. 2511

The basic concepts of an inspection system as proposed by NFI are incorporated in H.R. 2511. Legislative drafters and attorneys undoubtedly will find many details to discuss. Some major areas of concern with the bill as drafted include:

1) The provision for import inspections needs to be expanded to provide direction in terms of dealing with overseas governments, monitoring and port of entry surveillance.
2) The section on establishing acceptable levels of unavoidable contaminants needs considerable deliberation.

   Current law governing the presence of environmental contaminants in fish needs review and, in our opinion, change. Presently, toxic substances, pesticide residues, natural toxins are governed by different sections of the Food, Drug and Cosmetic Act, non of which was written with the presence of residues in fish in mind. The idea that fish is adulterated because of presence of an unregistered pesticide suggests that pesticide manufacturers will register their chemicals for use on fish. This is not plausible.

   Another section suggests that different criteria be used to determine tolerances if the residue is naturally occurring as opposed to being an additive. What is natural in these circumstances? The activities of mankind have changed the marine environment over thousands of years. It would seem that the marine environment, with all of its components, is the way nature is today. We believe a new section of law is needed to address environmental contaminants in fish products.

3) We are concerned about inclusion of the term "grading" in the section calling for establishment of standards. There already is a federal program which provides for grade standards. This is totally voluntary and should remain so.

4) The bill, of course, must eventually designate an agency. It will have to spell out the coordination between federal and state responsibilities and provide for transfer of authorities, facilities and personnel among agencies.

STATEMENT BY JO ANN SMITH
ASSISTANT SECRETARY OF AGRICULTURE FOR MARKETING AND INSPECTION SERVICES
BEFORE THE SUBCOMMITTEE ON FISHERIES AND WILDLIFE CONSERVATION AND THE ENVIRONMENT
COMMITTEE ON MERCHANT MARINE AND FISHERIES
U.S. HOUSE OF REPRESENTATIVES
JUNE 7, 1989

Mr. Chairman, on behalf of the U.S. Department of Agriculture (USDA), thank you for the opportunity to participate in this hearing concerning the issue of seafood safety and inspection.

As reflected in the proposed bill by the Chairman and Mr. Young, and the increasing concern voiced by consumer groups, public action organizations, the media and the industry, it is clear that the time has come for consideration of the steps needed to ensure the safety of seafood available for public consumption. This complex issue deserves serious scrutiny and debate.

The Administration recognizes the importance of the continuing assurance that the seafood products for public consumption are safe and is reviewing how best to accomplish this objective.

It is important to emphasize that the public health threat to Americans who are consuming fish and shellfish is not great. Seafood represents a small percentage of foodborne illnesses. Most of these illnesses are preventable through a strong consumer education program, although increased regulatory controls may also prove necessary.

Let me tell you what we are doing at USDA, specifically at the Food Safety and Inspection Service, about fulfilling our responsibilities and concerns for food safety.

THE INSPECTION PROGRAM OF THE FOOD SAFETY AND INSPECTION SERVICE

The USDA's Food Safety and Inspection Service (FSIS) is both a public health and regulatory agency. It administers a comprehensive system of inspection laws regulating meat and poultry products moving in interstate and foreign commerce for use as human food. The laws protect consumers by ensuring that the products are wholesome, unadulterated, and properly marked, labeled, and packaged. The laws protect packers by ensuring that no one gains an unfair economic advantage by putting unwholesome or misbranded products on the market.

Meat and poultry inspection activities, as carried out by FSIS, include a network of five regional offices, 26 area offices, and 189 inspection circuits. An FSIS work force of more than 7,000 inspectors enforces the inspection laws in some 6,900 meat and poultry slaughtering and processing plants all over the country. Only these federally inspected plants may sell their products in interstate or foreign commerce.

The FSIS appropriated operating budget for Fiscal Year 1989 is $405 million. Most of this amount finances Federal inspection activities, but $36.9 million is allotted for the Grants to States program, which pays up to half the cost for each of the 28 State inspection programs.

Inspection Work Force: FSIS successfully manages the largest food safety inspection force of any Federal agency. As of April 1989, 950 veterinarians, 132 food technologists and 5,949 food inspectors carried out inspection at 6,910 meat and poultry plants dispersed throughout the United States and its territories. In addition, 92 import inspection personnel examined meat and poultry imports at points of entry into the United States. FSIS has experience inspecting large numbers of small producers and processors. They also have demonstrated the capability to manage inspection resources, even accounting for seasonal fluctuation in slaughter and processing volume based on consumer demand.

Education and Training: FSIS has recently dedicated a new, state-of-the-art continuing education center located at Texas A&M University to provide targeted educational programs and retraining for FSIS staff.

HACCP Approach: FSIS employs aspects of the Hazard Analysis Critical Control Point (HACCP) system for managing inspection programs. The HACCP system consists of identification of the process flow, risk assessment and identification of critical control points (CCPs), and control and monitoring at those points.

Scientific Orientation: FSIS bases its regulatory decisions on scientific information. Meat and poultry are systematically sampled and tested for residues, microbes, parasites, additives, and species substitution. During Fiscal Year 1988 FSIS performed over 2,174,000 analyses on 463,634 samples.

Laboratory Facilities: The Science Field Staff Laboratories provide complete analytical support to the inspection and enforcement system. These state-of-the-art facilities are located at Athens, Georgia, St. Louis, Missouri, and Alameda, California. The laboratory staff has extensive experience analyzing for chemical residues, microbiological contamination, processed product composition, and economic adulteration. The FSIS science program also manages an extensive accredited laboratory program consisting of 315 non-Federal laboratories. Accreditation is in two broad categories for meat samples: 1) food composition; 2) specific chemical residues (animal drugs, pesticides, and environmental contaminants).

Labeling Approval System and Standards: FSIS maintains a mandatory prior label approval system for meat and poultry. Under the FSIS system, labels for all federally inspected domestic and imported meat and poultry products are reviewed for accuracy before the product can be marketed. This review requirement ensures that false or misleading statements do not appear on meat or poultry products. In addition, FSIS develops formal product standards of identity and composition and determines that ingredients are safe and appropriate for the products in which they are used.

Import and Export Inspection: FSIS has extensive experience inspecting meat and poultry imports from over 30 countries as well as certifying meat and poultry products for export to over 70 countries. To ensure safe imports, we routinely review foreign country inspection programs and certify facilities to ensure their ability to manufacture safe food. To ensure safe exports and facilitate foreign trade, FSIS provides certification of all U.S. meat and poultry products exported to foreign countries, stating that the products have been inspected and passed by U.S. inspectors and that the foreign countries' requirements have been met. FSIS also maintains an established network with foreign inspection officials.

Compliance: FSIS closely monitors products to ensure that they conform with ingredient and processing standards and labeling requirements. We also monitor businesses involved in the transportation, storage, and distribution of meat and poultry products. FSIS has established rigorous enforcement procedures for non-compliant product. During Fiscal Year 1988, the Compliance Division of FSIS reviewed approximately 56,000 cases resulting in 1,019 product detentions, 17 product recalls, and 24 convictions.

Consumer Education: Scientific studies have repeatedly revealed that many cases of foodborne illness can be prevented by proper food handling. FSIS now conducts an extensive public information program to educate consumers and institutional food handlers about the safe handling of meat and poultry. The program utilizes booklets, a magazine, background papers, fact sheets, feature stories, video news releases, and radio features. Some materials are available in Spanish.

In addition, FSIS operates a toll-free Meat and Poultry Hotline. The Hotline's specially trained home economists answer consumer questions about the safe handling, storage and preparation of meat and poultry.

Federal-State Relations: FSIS successfully monitors 28 State inspection programs, which inspect meat and poultry products that will be sold only in the State in which they were produced. By law, State inspection programs are required to be "at least equal to" the Federal inspection program. If States choose to discontinue their inspection programs or cannot maintain this standard, FSIS must assume responsibility for inspection.

FSIS's Federal-State relations staff assures that State inspection programs enforce requirements at least equal to those of Federal inspection. This staff also gives technical assistance to plants operating under the Talmadge-Aiken Act, which established agreements permitting State employees to carry out inspection in federally inspected plants.

FSIS also has well established links and Memoranda of Understanding with other Federal agencies, including the Centers for Disease Control (responsible for reporting foodborne illnesses), the Environmental Protection Agency (responsible for chemical residue tolerances), and the Food and Drug Administration (responsible for animal drug residue tolerances).

CONCLUSION

This concludes my prepared testimony, Mr. Chairman. I will gladly answer any questions you and the subcommittee members may have.

NATIONAL RESEARCH COUNCIL

2101 CONSTITUTION AVENUE WASHINGTON, D. C. 20418

OFFICE OF THE CHAIRMAN

JUN - 7 1989

May 31, 1989

Gerry E. Studds
Chairman
Subcommittee on Fisheries and Wildlife
Conservation and the Environment
U.S. House of Representatives Committee
on Merchant Marine and Fisheries
Room 1334, Longworth House Office Building
Washington, D.C. 20515-6230

Dear Congressman Studds:

Thank you for your letter of May 16, inviting my participation in the hearing on seafood safety and inspection, scheduled for June 7, 1989. I want to congratulate the Subcommittee on its foresight in addressing this critical issue of national importance. You will be pleased to learn that an expert panel of our Institute of Medicine's Food and Nutrition Board is currently addressing several of the topics you have raised. Our study was commissioned by the National Marine Fisheries Service and will be completed by December 1990. At that time, we expect to provide you with a detailed assessment of the safety of seafood, which we hope can serve as a comprehensive basis for policy actions. Thank you for you support of this important effort.

In the interim, we recognize that the Subcommittee on Fisheries and Wildlife Conservation and the Environment must continue to address seafood safety issues. Therefore, I want to bring to your attention issues which have already been raised by our expert panel, and which we hope will assist the Subcommittee in its deliberations.

As you know, the National Research Council (NRC) has previously offered advice on the adequacy of the federal meat and poultry inspection system. These earlier efforts were constrained by the limitations of preestablished regulatory systems, which were put in place nearly a century ago. Those systems were established prior to detailed knowledge and an in-depth assessment of the public health risks and the best approach for addressing them. We are encouraged that federal agencies are now beginning to implement the many steps proposed by the previous NRC panels to improve the monitoring of meat and poultry safety.

For seafood, we have a unique opportunity to study the problems denovo and consider innovative approaches -- approaches that specifically take into account the vast variety of seafood species and the diverse nature of the seafood industry. For example, unlike meat and poultry, for which the industry is more consolidated, and for which the U.S. relies primarily on domestic production, the fish and shellfish industry relies on the importation of stocks from scores of countries. This imported stock accounts for more than half of the seafood consumed in the United States. Furthermore, recreational fishing accounts for a significant new proportion of the

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fisheries catch and poses significant management challenges. In addition, unlike meat and poultry, for which the production environment is restricted and relatively controlled, the harvesting, production, and distribution environment for seafood is broad and diverse. These differences between the seafood industry and the meat and poultry industry exemplify issues that require special attention to identify the sources and types of risks that are special to seafoods, and which may have a specific impact on the health of the American people. Nevertheless, our earlier NRC reports on meat and poultry will contribute substantially to our assessment of seafoods.

These are only a few of the fundamental issues currently being examined by our expert panel. We hope to have an opportunity to give you a report by December 1990, which will provide an assessment of the problem as well as options for monitoring seafood safety.

Thank you again for the opportunity to comment on this very important matter.

Sincerely,

Frank Press
Chairman

SUBMISSION FOR THE RECORD

COMMITTEE ON MERCHANT MARINE AND FISHERIES
SUBCOMMITTEE ON FISHERIES AND WILDLIFE CONSERVATION
AND THE ENVIRONMENT
HOUSE OF REPRESENTATIVES
JUNE 7, 1989

SUBMISSION: Copies of the Food and Drug Administration (FDA)/Centers for Disease Control (CDC) correspondence regarding risk assessments for seafood as compared to other sources of muscle protein.

1. FDA letter dated May 19, 1989 with copy of draft risk assessment.
2. CDC response letter dated May 31, 1989
3. FDA's revised risk assessment based on CDC comments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

1

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 19, 1989

Dr. Walter Dowdle
Acting Director, Centers for
Disease Control
Office of the Director
Mail Stop D-14
Bldg. 1, Room 2000
Centers for Disease Control
1600 Clifton Road, N.E.
Atlanta, Georgia 30333

Walt
Dear Dr. Dowdle:

As you may know, FDA faces several upcoming Congressional hearings regarding seafood inspection. In preliminary informational meetings with Congressional staffers, we have been asked countless times, "what is the public health risk from seafood?" and "how does the public health risk from seafood compare with other muscle protein foods?" Although we can respond to these questions instinctively, the answer to the questions in large part depends on estimated actual incidence of specific diseases and what proportion of each disease can be ascribed to a specific commodity. CDC is recognized as the authority on such matters, and CDC's opinion counts far more than FDA's in this regard.

Scientists at our Center for Food Safety and Applied Nutrition have attempted to develop an analysis of risk, based on best available estimates of actual cases of disease, and compared on a pound for pound basis using best available, weight corrected consumption data. I am requesting that you have CDC's experts examine this analysis critically. I would appreciate your comments as to the validity of the approach, the validity of the assumptions and data on which the risk analysis is based, and particularly, whether the rank order of risk attributed to various foods is the most probable correct scenario for the United States.

In your analysis it is important to recognize that we intend to make these data public information. We believe this is necessary to factually reflect the public health risks associated with the consumption of muscle protein. I would greatly appreciate a prompt reply to this request and many thanks.

Sincerely yours,

Frank E. Young, M.D., Ph.D.
Commissioner of Food and Drugs

Enclosure

CONTINUOUS INSPECTION OF MEAT & POULTRY: SHOULD IT BE APPLIED TO SEAFOOD?

1. **Meat and Poultry Inspection - 1985 National Research Council Report**

* "*Salmonella* spp. and *Campylobacter jejuni* are the currently recognized major poultry-borne causes of illness in consumers; antemortem and postmortem inspection methods are inadequate to detect these organisms."

* *Salmonella* isolated from 2.5% to 87.5% of market-ready broiler chickens." (Recent work by Dr. Lillard, ARS, USDA, Athens, GA, has shown that single carcass rinse cannot accurately determine frequency of contamination. *Salmonella* attaches firmly to poultry skin and is not removed by up to 40 such washes).

2. **Poultry Inspection: The Basis for Risk-Assessment Approach- 1987 National Research Council Report**

* "The committee concludes that the present system of continuous inspection provides little opportunity to detect or control the most significant health risks associated with broiler chickens".

* "There is evidence linking disease in humans to the presence of pathogens on chickens. For example, epidemiological studies indicate that approximately 48% of *Campylobacter* infections are attributable to chicken. Data also suggest that chicken is probably an important source of salmonellosis in the United States."

* "In the 1984 SKCDPH (Seattle-King County Department of Health) study.....the relative risk for chicken consumption (re. campylobacteriosis) was 2.4; for rare or raw chicken, 7.6; for cooked chicken, 2.3." (The method of Walter was used to estimate 48.2% *Campylobacter jejuni* cases attributable to eating chicken. "The link between chicken and human illness was reinforced by finding similarities in antibiograms, plasmid content, and serotypes from poultry (retail) and human cases (isolates)".

* "Data for attributable risk (for *Salmonella*) are not as complete as those for *C. jejuni*, but numerous epidemiological studies document a major role for broiler chickens as a vehicle for salmonellosis in humans."

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- "Major changes are required in the poultry inspection system if public health is to be protected and if the investment of resources is to have maximum effect".
- Campylobacter has been isolated from 2.5% to 85% of consumer-ready poultry."

……………………………………………………………

From CDC Published Data - Outbreaks of salmonellosis, 1973-1984 by vehicle:

Finfish	5
Shellfish	2
Beef/veal/pork/lamb	96
Chicken	19
Turkey	33
Unknown	211
Total	597

From CDC Published Data - From 1978-1984, no outbreaks of campylobacteriosis have been attributed to finfish or shellfish.

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Estimates of Number of Cases Annually in the United States:

1. Campylobacteriosis: 2,000,000 to 4,000,000 cases, mostly sporadic
   48 to 480 deaths

Poultry- 1) outbreak-associated (very little)
2) sporadic cases - 48% to 70% of total cases

Finfish- 1) no outbreaks yet reported
2) no association with sporadic cases

Shellfish- 1) one outbreak reported (not to CDC)
2) no association with sporadic cases

But- The Seattle-King County HMO study showed an increased risk for campylobacteriosis associated with raw or undercooked fish. The problem may be one of isolating Campylobacter from the marine environment.

Besides fatalities, which are less frequent than Salmonella-associated deaths, Campylobacter can lead to reactive arthritis, organ infections, septicemia, and Guillain-Barre syndrome.

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2. Salmonellosis: 400,000 to 4,000,000 cases, both in outbreaks and sporadic
500 deaths

Poultry- 1) outbreak-associated - 9.5%
2) sporadic case-associated - (*thought to be a major cause by both NRC committees)
20 to 30% sporadic cases would appear to be chicken related by serotype

Finfish- 1) outbreak-associated - less than 1%
2) sporadic case-associated - unknown

Shellfish- 1) outbreak-associated - less than 0.5%
2) sporadic case-associated - unknown

Besides deaths, *Salmonella* infections can frequently cause septicemia, specific organ infections, and reactive arthritis.

……

SEAFOOD-ASSOCIATED DISEASES

1. FINFISH- Ciguatera and Scombroid poisonings account for 82% of confirmed seafood-related illnesses. CDC feels that most are reported because of rapid onset and nature of symptoms.

Ciguatera - Avg # outbreaks annually = 16.5
Avg # cases per outbreak = 4.6
Avg # cases annually = 76
Deaths annually - 3 *ever* reported

Scombroid - Avg # outbreaks annually = 15
Avg # cases per outbreak = 4.25
Avg # cases annually = 64
Deaths annually - 1 *ever* reported

Anasakiasis - Estimated avg # cases annually = 5

Salmonellosis - Avg # outbreaks annually = 0.5
Avg # cases per outbreak = 51
Avg # cases annually = 25

Other (e.g., vibrios) - sporadic cases by cross-contamination have occurred (e.g., cooked crabs)

Staphylococcal food poisoning - some attributable to picked products (e.g., crabmeat, shrimp)

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2. SHELLFISH- A wider spectrum of pathogens are associated with shellfish, particularly with raw shellfish.

Vibrio infections (non-lethal) - estimated 5000 to 10,000

Vibrio vulnificus - 20 deaths annually (cirrhotics)

Salmonellosis - Estimated cases annually - 100 to 1,000

Acute, non-lethal viruses - Reported cases annually = 4-500
(Norwalk,Norwalk-like) Estimated cases annually = ? but
could be 4,000 to 50,000
These are increasing!

Hepatitis A - Reported cases annually - 10
Estimated cases annually- less than 100
Deaths annually - 1

From GAO Report - Seafood Safety: Seriousness of the Problem and Efforts to Protect Consumers - August, 1988 - to the Chairman, Subcommittee on Commerce, Consumer and Monetary Affairs, Committee on Government Operations, House of Representatives

Comparison of Reported Seafood Illness Outbreaks, Cases, and Deaths With All Food Illness for the Period 1978-1984 (Compiled by GAO from CDC published & unpublished data)

Categories	Seafood-related _Illness_	All Food-related _Illness_	Seafood as % of _all food_
Outbreaks	368	3,770	9.76
Cases	5,080	100,166	5.07
Deaths	5	141	3.55

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Estimate of Seafood-Associated vs Chicken-Associated Diseases by Estimated Actual Number of Cases of Disease Annually:

** Beef and other red meats were not estimated, as no good case-control studies have been done as with chicken.

Estimates used: 2,000,000 cases salmonellosis annually - 500 deaths
*Source- Estimate from Carter Center/ CDC Report, based on 1983 data. Deaths subsequently lowered to 500 from 2000 in Carter Center.

2,100,000 cases campylobacteriosis annually - 48 - 480 deaths
*Source- Estimate from Carter Center/ CDC Report. Deaths adjusted downward subsequent to that report.

The estimates of salmonellosis and campylobacteriosis are most likely low side estimates in light of more recent reports.

1,700 cases listeriosis annually- 415 deaths
*Source- Gellin & Broome, JAMA.1989. Data is from FDA-funded prospective case-control study.

48 to 70% sporadic campylobacteriosis - attributable to chicken
*Source- 1987 testimony of Dr. M. Cohen, DBD, CID, CDC at Stenholm Hearing; based on Seattle-King County and Georgia case-control studies.

20% to 30% of sporadic salmonellosis - attributable to chicken.
*Source- CDC estimate based on chicken-specific Salmonella isolates sent to CDC (from human sources)

4% sporadic listeriosis - attributable to chicken
*Source- Schwartz et al. 1988. Ann Int Med (FDA-funded prospective surveillance)

15.4 pounds seafood consumed per capita or 3.7 Billion pounds per year. @

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43.4 pounds chicken consumed per capita
or 10.4 Billion pounds per year. @
@ - adjusted to edible weight consumed.

Less than 0.1% seafood consumed as raw
shellfish- This is an assumption,
but is quite defensible.

Used 3.7 billion pounds consumed for both all seafood (including raw molluscan shellfish) and for fish (excluding raw molluscan shellfish) because raw shellfish are 0.1% or less of the total weight consumed.

1. Chicken - Estimate of individual cases of disease and death caused annually based on above estimates:

   a.) Campylobacteriosis:
   Low side- 48% of 2.1 million cases = 1,008,000
   High Side- 70% of 2.1 million cases = 1,470,000

   Deaths from campylobacteriosis:
   Low side- 48% of 48 = 23
   High side- 70% of 480 = 336

   b.) Salmonellosis:
   Low side- 20% of 2 million cases = 400,000
   high side- 30% of 2 million cases = 600,000

   Deaths from salmonellosis:
   Low side- 20% of 500 = 100
   High side- 30% of 500 = 150

   c.) Listeriosis:
   4% of 1700 cases = 68

   Deaths from listeriosis: 4% of 415 = 17

   d.) Case and Death totals:

   Disease cases annually:

   Low side- 1,008,000 + 400,000 + 68 = 1,408,068
   High side- 1,470,000 + 600,000 + 68 = 2,070,068

   Deaths annually:

   Low side- 23 + 100 + 17 = 140
   High side- 336 + 150 + 17 = 503

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e.) Cases and Deaths expressed as number annually per billion pounds consumed:

Disease cases:

Low- $\frac{1,408,068}{10.4}$ = 135,391 cases/billion pounds

High- $\frac{2,070,068}{10.4}$ = 199,045 cases/billion pounds

Deaths:

Low- $\frac{140}{10.4}$ = 13.5/billion lbs

High- $\frac{503}{10.4}$ = 48 deaths/billion pounds

2. Shellfish: (based on estimate of 0.1% or less consumed raw)

Vibrios (non-lethal) = 10,000 per year (high estimate)
Deaths (*V.vulnificus*) = 20

Salmonellosis = 1,000 cases per year (high estimate)

Viruses (non-lethal) = 50,000 (High estimate)

Hepatitis A = 100 cases ; 1 death

3.7 billion lbs seafood X 0.1% (eaten raw) = 3.7 million lbs

10,000 + 1,000 + 50,000 + 100 = 61,100 cases disease / year
(based on all high side estimates)

$\frac{61,100 \text{ cases disease}}{0.0037 \text{ billion lbs consumed}}$ (high estimate) = 16,513,513 cases per billion lbs

Deaths = $\frac{21}{0.0037}$ = 5676 deaths per billion lbs

***BUT- 3.7 million lbs consumed raw is estimate only.

3. Finfish (includes crustaceans)- Estimate of annual incidence of disease and death based on previously listed estimates:

a.) cases of ciguatera + scombroid = 76 + 64 = 140

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140 reported X 10 (estimated multiplier for possible sporadic cases) = 1400 cases
Deaths per year: 0

b.) Anasakiasis- Estimated 5 cases annually (raw fish)

c.) Salmonellosis cases from outbreaks = 25
25 X 29 (multiplier used by F. Bryan) = 725 cases
Deaths annually from salmonellosis = 1

d.) Possible sporadic cases of vibrio infection by cross-contamination = 500 (estimate)

e.) Possible staphylococcal food poisoning (hand picked seafoods) = 500 cases

f.) Estimated total disease from finfish annually:

1400 + 5 + 725 + 500 + 500 = 3130 cases of disease annually

Estimated deaths = 1

g.) Illnesses and deaths per billion pounds consumed:

$\frac{3130 \text{ cases}}{3.7}$ = 896 cases of disease/billion pounds/year

$\frac{1 \text{ death}}{3.7}$ = 0.27 deaths/billion pounds/year

4. Shellfish + Finfish (all other seafood) - Total diseases and deaths caused annually by all seafoods:

61,100 + 3130 = 64,230 total cases of seafood-associated disease annually

Deaths: 21 + 1 = 22

Calculated as cases or deaths per billion pounds consumed:

$\frac{64,230}{3.7}$ = 17359 cases of disease/billion pounds/year

$\frac{22}{3.7}$ = 6 deaths/billion pounds/year

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RELATIVE RISKS FOR DISEASE & DEATH
(based on billion pounds consumed)

I. Estimates Summary:

1. Chicken:

Illnesses - 135,391 to 199,045 illnesses per billion pounds consumed per year

Deaths - 13.5 to 48 deaths per billion pounds consumed per year

2. Raw Molluscan Shellfish:

Illnesses - 16,513,513 illnesses per billion pounds consumed per year

Deaths - 5,676 deaths per billion pounds consumed per year

3. Fish (including all finfish, crustaceans, etc., but NOT raw molluscan shellfish:

Illnesses - 896 illnesses per billion pounds consumed per year

Deaths - 0.27 deaths per billion pounds consumed per year

4. All Seafoods (sum of 2 and 3 above):

Illnesses - 17,359 illnesses per billion pounds consumed per year

Deaths - 6 deaths per billion pounds consumed per year

COMPARATIVE RISKS

1. Chicken vs All Seafoods (1 vs 4 above):

Compared on a pound for pound consumed basis:

Chicken is 7.8 to 11.5 times more likely to make you ill than seafood

Chicken is 2 to 8 times more likely to result in death

DRAFT

than seafood

2. Chicken vs Fish (the 99.9+% of finfish, crustaceans, etc., but excluding raw molluscan shellfish):

   Compared on a pound for pound consumed basis:

   - Chicken is 150 to 220 times more likely to make you ill than fish (excluding raw molluscan shellfish)

   - Chicken is 50 to 180 times more likely to result in death than fish

3. Raw Molluscan Shellfish vs Chicken:

   Compared on a pound for pound consumed basis:

   - Raw molluscan shellfish are 83 to 122 times more likely to make you ill than chicken

   - Raw molluscan shellfish are 118 to 420 times more likely to result in death than chicken (deaths almost exclusively limited to persons with cirrhosis from *V. vulnificus*)

4. Raw Molluscan Shellfish vs Fish (all fish, crustaceans, etc., excluding the estimated 0.1% shellfish consumed raw):

   Compared on a pound for pound consumed basis:

   - Raw molluscan shellfish are 18,430 times more likely to make you ill than fish

   - Raw molluscan shellfish are 21,000 times more likely to result in death than fish

PLACING THINGS IN PERSPECTIVE

The following values are estimates of the risk of disease from a 4 ounce serving of the specified commodity:

1. Chicken: About one illness episode will occur per 25,000 servings

2. All Seafood (including raw molluscan shellfish):

   About 1 illness episode will occur per 250,000 servings

3. Fish (all varieties, 99.9+% consumed annually, excluding raw molluscan shellfish:

   About 1 illness episode will occur per 5,000,000 servings

4. Raw molluscan shellfish:

   About 1 illness episode will occur per 250 servings (of 4 ounces)

Conclusions: It should be noted that even relatively large errors in the base estimates in the frequency of occurrence of individual diseases or percents of disease attributable to a specific commodity would not have a major impact on the relative risk or rank order of risk.

One must also consider the TOTAL impact of the specific diseases. For example, Norwalk agent causes the bulk of raw shellfish-associated disease, but is a mild, short-lived illness, with no attributable mortality. V. vulnificus contributes virtually all risk of disease from raw shellfish, but deaths are almost exclusively limited to persons with cirrhosis. In contrast, salmonellosis and campylobacteriosis cause acute gastrointestinal disease in nearly all persons, and the disease can last from 1 to 7 days or more. Campylobacter and Salmonella can trigger unpleasant, serious, long-lasting sequelae, and cause death in a broader spectrum of individuals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

MAY 31 1989

Frank E. Young, M.D., Ph.D.
Commissioner of Food and Drugs
Room 14-71, Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Frank:

Thank you for your letter requesting our assessment of the Food and Drug Administration's (FDA) estimates of relative risk of foodborne illness due to chicken, fish, and shellfish.

The FDA document develops estimates of the relative risk of acquiring foodborne disease by eating raw molluscan shellfish, other seafoods (referred to as "fish"), or chicken. The analysis is an extrapolation using a series of estimates: total number of cases and deaths due to specific foodborne diseases, the proportion that could be attributed to each of the food vehicles, and the amount of each food vehicle consumed. Centers for Disease Control (CDC) staff comments on these data are provided below; we cannot comment on the estimates of food consumption.

1. The FDA risk model includes the major foodborne diseases that can be attributed to raw shellfish, chicken, and fish. The estimates for the total annual number of cases, number of deaths, and percent of cases due to each of the three food groups agree in general with reported data or represent reasonable estimates.

2. It should be emphasized that the model is comparing seafoods with one food which is now being inspected, chicken. It does not cover all foodborne disease. In particular, it does not address disease associated with red meat. Thus, morbidity and mortality associated with products such as ham (an important cause of staphylococcal foodborne disease) and ground beef (an important cause of *Salmonella* and *E. coli* O157:H7 infections) are not included.

3. All ciguatera and scombroid outbreaks are related to finfish.

4. The estimates supported by solid epidemiologic evidence include the estimates of *Listeria*, or the range of *Campylobacter* infections attributable to chicken. (However, the CDC estimate for listeriosis [Schwartz et al. 1988] cites 6 percent [rather than 4 percent] for the proportion of listeriosis attributable to poultry and the proportion of listeriosis associated with seafoods, although as yet unknown, is not likely to be zero.)

5. Shellfish-associated Norwalk and Norwalk-like virus infections are acquired from eating either raw or partially cooked shellfish; inclusion of those cases under "raw shellfish" may be inaccurate unless the estimate of the amount of raw shellfish consumed also includes shellfish eaten partially cooked. The single death attributable to salmonellosis in the cases due to finfish could be matched by a death due to salmonellosis caused by shellfish.

6. Outbreaks of staphylococcal food poisoning can follow contamination of any protein-rich food, not just fish; and more outbreaks of staphylococcal food poisoning have been reported from pork products than from poultry, fish, and shellfish combined.

7. Several hundred cases of hepatitis A may be associated with shellfish, with up to one death.

8. Many of the numbers are simply best estimates, as in the risk model. The data do not exist which would allow greater precision. For example, the proportion of salmonellosis due to any particular food vehicle is not known. Chicken has been associated with only a small proportion of outbreaks of salmonellosis, but some scientists have estimated that it could account for more than 50 percent of sporadic cases; only an epidemiologic study of sporadic salmonellosis would clarify this. The method used in this analysis, based on "chicken-associated serotypes," provides a defensible guess in the absence of better data.

9. In the instances in which estimates are given as a range, a reasonable approach would be to use midpoints.

10. The final risk estimates for raw molluscan shellfish, chicken, and fish are separated from each other by two orders of magnitude. Thus, small differences in estimates are not likely to produce major changes in the ranking of these foods as causes of foodborne illness. This analysis suggests that compared to eating chicken, there is considerable hazard in eating raw shellfish and relative safety in eating other seafoods. This conclusion about the relative risk of various foods is consistent with the impressions that we have gained from our multiple investigations of foodborne disease and of specific pathogens.

We appreciate the opportunity to comment on your document.

Sincerely yours,

Walter R. Dowdle, Ph.D.
Acting Director

3

CONTINUOUS INSPECTION OF MEAT & POULTRY: SHOULD IT BE APPLIED TO SEAFOOD?

1. **Meat and Poultry Inspection - 1985 National Research Council Report**

* "*Salmonella* spp. and *Campylobacter jejuni* are the currently recognized major poultry-borne causes of illness in consumers; antemortem and postmortem inspection methods are inadequate to detect these organisms."

* *Salmonella* isolated from 2.5% to 87.5% of market-ready broiler chickens." (Recent work by Dr. Lillard, ARS, USDA, Athens, GA, has shown that single carcass rinse cannot accurately determine frequency of contamination. *Salmonella* attaches firmly to poultry skin and is not removed by up to 40 such washes).

2. **Poultry Inspection: The Basis for Risk-Assessment Approach-1987 National Research Council Report**

* "The committee concludes that the present system of continuous inspection provides little opportunity to detect or control the most significant health risks associated with broiler chickens".

* "There is evidence linking disease in humans to the presence of pathogens on chickens. For example, epidemiological studies indicate that approximately 48% of *Campylobacter* infections are attributable to chicken. Data also suggest that chicken is probably an important source of salmonellosis in the United States."

* "In the 1984 SKCDPH (Seattle-King County Department of Health) study.....the relative risk for chicken consumption (re. campylobacteriosis) was 2.4; for rare or raw chicken, 7.6; for cooked chicken, 2.3." (The method of Walter was used to estimate 48.2% *Campylobacter jejuni* cases attributable to eating chicken. "The link between chicken and human illness was reinforced by finding similarities in antibiograms, plasmid content, and serotypes from poultry (retail) and human cases (isolates)".

* "Data for attributable risk (for *Salmonella*) are not as complete as those for *C. jejuni*, but numerous epidemiological studies document a major role for broiler chickens as a vehicle for salmonellosis in humans."

- "Major changes are required in the poultry inspection system if public health is to be protected and if the investment of resources is to have maximum effect".

- Campylobacter has been isolated from 2.5% to 85% of consumer-ready poultry."

……

From CDC Published Data - Outbreaks of salmonellosis, 1973-1984 by vehicle:

Finfish	5
Shellfish	2
Beef/veal/pork/lamb	96
Chicken	19
Turkey	33
Unknown	231
Total	597

From CDC Published Data - From 1978-1984, no outbreaks of campylobacteriosis have been attributed to finfish or shellfish.

……

Estimates of Number of Cases Annually in the United States:

1. Campylobacteriosis: 2,000,000 to 4,000,000 cases, mostly sporadic
48 to 480 deaths

Poultry- 1) outbreak-associated (very little)
2) sporadic cases - 48% to 70% of total cases

Finfish- 1) no outbreaks yet reported
2) no association with sporadic cases

Shellfish- 1) one outbreak reported (not to CDC)
2) no association with sporadic cases

But- The Seattle-King County HMO study showed an increased risk for campylobacteriosis associated with raw or undercooked fish. The problem may be one of isolating Campylobacter from the marine environment.

Besides fatalities, which are less frequent than Salmonella-associated deaths, Campylobacter can lead to reactive arthritis, organ infections, septicemia, and Guillain-Barre syndrome.

2. Salmonellosis: 400,000 to 4,000,000 cases, both in outbreaks and sporadic
500 deaths

Poultry- 1) outbreak-associated - 9.5%
2) sporadic case-associated - (*thought to be a major cause by both NRC committees)
20 to 30% sporadic cases would appear to be chicken related by serotype

Finfish- 1) outbreak-associated - less than 1%
2) sporadic case-associated - unknown

Shellfish- 1) outbreak-associated - less than 0.5%
2) sporadic case-associated - unknown

Besides deaths, _Salmonella_ infections can frequently cause septicemia, specific organ infections, and reactive arthritis.

……

SEAFOOD-ASSOCIATED DISEASES

1. FINFISH- Ciguatera and Scombroid poisonings account for 82% of confirmed seafood-related illnesses. Because of the dramatic and unusual symptoms, there is a higher likelihood of these poisonings being reported, and little question as to food association.

Ciguatera - Avg # outbreaks annually = 16.5
Avg # cases per outbreak = 4.6
Avg # cases annually = 76
Deaths annually - 3 _ever_ reported

Scombroid - Avg # outbreaks annually = 15
Avg # cases per outbreak = 4.25
Avg # cases annually = 64
Deaths annually - 1 _ever_ reported

Anasakiasis - Estimated avg # cases annually = 5

Salmonellosis - Avg # outbreaks annually = 0.5
Avg # cases per outbreak = 51
Avg # cases annually = 25

- * Other (e.g., vibrios) - sporadic cases by cross-contamination have occurred (e.g., cooked crabs)
- * Staphylococcal food poisoning - some attributable to picked products (e.g., crabmeat, shrimp)

2. SHELLFISH- (Raw or Partially Cooked) A wider spectrum of pathogens are associated with shellfish, particularly with raw shellfish.

Vibrio infections (non-lethal) - estimated 5000 to 10,000

Vibrio vulnificus - 20 deaths annually (cirrhotics)

Salmonellosis - Estimated cases annually - 100 to 1,000

Acute, non-lethal viruses - Reported cases annually = 4-500
(Norwalk,Norwalk-like)   Estimated cases annually = ? but
                            could be 4,000 to 50,000
                            These are increasing!

Hepatitis A - Reported cases annually - 10
              Estimated cases annually- less than 100
              Deaths annually - 1

From GAO Report - Seafood Safety: Seriousness of the Problem and Efforts to Protect Consumers - August, 1988 - to the Chairman, Subcommittee on Commerce, Consumer and Monetary Affairs, Committee on Government Operations, House of Representatives

Comparison of Reported Seafood Illness Outbreaks, Cases, and Deaths With All Food Illness for the Period 1978-1984 (Compiled by GAO from CDC published & unpublished data)

Categories	Seafood-related Illness	All Food-related Illness	Seafood as % of all food
Outbreaks	368	3,770	9.76
Cases	5,080	100,166	5.07
Deaths	5	141	3.55

....

Estimate of Seafood-Associated vs Chicken-Associated Diseases by Estimated Actual Number of Cases of Disease Annually:

** Beef and other red meats were not estimated, as no good case-control studies have been done as with chicken.

Estimates used:

2,000,000 cases salmonellosis annually - 500 deaths
*Source- Estimate from Carter Center/CDC Report, based on 1983 data. Deaths subsequently lowered to 500 from 2000 in Carter Center.

2,100,000 cases campylobacteriosis annually - 48 - 480 deaths
*Source- Estimate from Carter Center/CDC Report. Deaths adjusted downward subsequent to that report.

The estimates of salmonellosis and campylobacteriosis are most likely low side estimates in light of more recent reports.

1,700 cases listeriosis annually- 415 deaths
*Source- Gellin & Broome, JAMA.1989. Data is from FDA-funded prospective case-control study.

48 to 70% sporadic campylobacteriosis - attributable to chicken
*Source- 1987 testimony of Dr. M. Cohen, DBD, CID, CDC at Stenholm Hearing; based on Seattle-King County and Georgia case-control studies.

20% to 30% of sporadic salmonellosis - attributable to chicken.
*Source- CDC estimate based on chicken-specific *Salmonella* isolates sent to CDC (from human sources)

4% sporadic listeriosis - attributable to chicken
*Source- Schwartz et al. 1988. Ann Int Med (FDA-funded prospective surveillance)

15.4 pounds seafood consumed per capita or 3.7 Billion pounds per year. @

43.4 pounds chicken consumed per capita or 10.4 Billion pounds per year. @
@ = adjusted to edible weight consumed.

Less than 0.1% seafood consumed as raw shellfish- This is an assumption, but is quite defensible.

Used 3.7 billion pounds consumed for both all seafood (including raw molluscan shellfish) and for fish (excluding raw molluscan shellfish) because raw or partially cooked shellfish are 0.1% or less of the total weight consumed.

1. Chicken - Estimate of individual cases of disease and death caused annually based on above estimates:

a.) Campylobacteriosis:
Low side- 48% of 2.1 million cases = 1,008,000
High Side- 70% of 2.1 million cases = 1,470,000

Deaths from campylobacteriosis:
Low side- 48% of 48 = 23
High side- 70% of 480 = 336

b.) Salmonellosis:
Low side- 20% of 2 million cases = 400,000
high side- 30% of 2 million cases = 600,000

Deaths from salmonellosis:
Low side- 20% of 500 = 100
High side- 30% of 500 = 150

c.) Listeriosis:
4% of 1700 cases = 68

Deaths from listeriosis: 4% of 415 = 17

d.) Case and Death totals:

Disease cases annually:

Low side- 1,008,000 + 400,000 + 68 = 1,408,068
High side- 1,470,000 + 600,000 + 68 = 2,070,068

Deaths annually:

Low side- 23 + 100 + 17 = 140
High side- 336 + 150 + 17 = 503

e.) Cases and Deaths expressed as number annually per billion pounds consumed:

Disease cases:

Low- $\frac{1,408,068}{10.4}$ = 135,391 cases/billion pounds

High- $\frac{2,070,068}{10.4}$ = 199,045 cases/billion pounds

Deaths:

Low- $\frac{140}{10.4}$ = 13.5/billion lbs

High- $\frac{503}{10.4}$ = 48 deaths/billion pounds

2. Shellfish: (based on estimate of 0.1% or less consumed raw or partially cooked)

Vibrios (non-lethal) = 10,000 per year (high estimate)
Deaths (*V. vulnificus*) = 20

Salmonellosis = 1,000 cases per year (high estimate)

Viruses (non-lethal) = 50,000 (High estimate)

Hepatitis A = 100 cases ; 1 death

3.7 billion lbs seafood X 0.1% (eaten raw) = 3.7 million lbs

10,000 + 1,000 + 50,000 + 100 = 61,100 cases disease / year
(based on all high side estimates)

$\frac{61,100}{0.0037}$ $\frac{\text{cases disease}}{\text{billion lbs consumed}}$ (high estimate) = 16,513,513 cases per billion lbs

Deaths = $\frac{21}{0.0037}$ = 5676 deaths per billion lbs

***BUT- 3.7 million lbs consumed raw is estimate only.

3. Finfish (includes crustaceans)- Estimate of annual incidence of disease and death based on previously listed estimates:

a.) cases of ciguatera + scombroid = 76 + 64 = 140
140 reported X 10 (estimated multiplier for possible sporadic cases) = 1400 cases
Deaths per year: 0

b.) Anasakiasis- Estimated 5 cases annually (raw fish)

c.) Salmonellosis cases from outbreaks = 25
25 X 29 (multiplier used by F. Bryan) = 725 cases
Deaths annually from salmonellosis = 1

d.) Possible sporadic cases of vibrio infection by cross-contamination = 500 (estimate)

e.) Possible staphylococcal food poisoning (hand picked seafoods) = 500 cases

f.) Estimated total disease from finfish annually:

1400 + 5 + 725 + 500 + 500 = 3130 cases of disease annually

Estimated deaths = 1

g.) Illnesses and deaths per billion pounds consumed:

$\frac{3130 \text{ cases}}{3.7}$ = 896 cases of disease/billion pounds/year

$\frac{1 \text{ death}}{3.7}$ = 0.27 deaths/billion pounds/year

4. Shellfish + Finfish (all other seafood) - Total diseases and deaths caused annually by all seafoods:

61,100 + 3130 = 64,230 total cases of seafood-associated disease annually

Deaths: 21 + 1 = 22

Calculated as cases or deaths per billion pounds consumed:

$\frac{64{,}230}{3.7}$ = 17359 cases of disease/billion pounds/year

$\frac{22}{3.7}$ = 6 deaths/billion pounds/year

RELATIVE RISKS FOR DISEASE & DEATH
(based on billion pounds consumed)

I. Estimates Summary:

1. Chicken:

Illnesses - 135,391 to 199,045 illnesses per billion pounds consumed per year

Deaths - 13.5 to 48 deaths per billion pounds consumed per year

2. Raw/Partially Cooked Molluscan Shellfish:

Illnesses - 16,513,513 illnesses per billion pounds consumed per year

Deaths - 5,676 deaths per billion pounds consumed per year

3. Fish (including all finfish, crustaceans, etc., but NOT raw/partially cooked molluscan shellfish:

Illnesses - 896 illnesses per billion pounds consumed per year

Deaths - 0.27 deaths per billion pounds consumed per year

4. All Seafoods (sum of 2 and 3 above):

Illnesses - 17,359 illnesses per billion pounds consumed per year

Deaths - 6 deaths per billion pounds consumed per year

COMPARATIVE RISKS

1. Chicken vs All Seafoods (1 vs 4 above):

Compared on a pound for pound consumed basis:

Chicken is 7.8 to 11.5 times more likely to make you ill than seafood

Chicken is 2 to 8 times more likely to result in death than seafood

2. Chicken vs Fish (the 99.9+% of finfish, crustaceans, etc., but excluding raw/partially cooked molluscan shellfish):

   Compared on a pound for pound consumed basis:

   Chicken is 150 to 220 times more likely to make you ill than fish (excluding raw/partially cooked molluscan shellfish)

   Chicken is 50 to 180 times more likely to result in death than fish

3. Raw/partially cooked Molluscan Shellfish vs Chicken:

   Compared on a pound for pound consumed basis:

   Raw/partially cooked molluscan shellfish are 83 to 122 times more likely to make you ill than chicken

   Raw/partially cooked molluscan shellfish are 118 to 420 times more likely to result in death than chicken (deaths almost exclusively limited to persons with cirrhosis from V. vulnificus)

4. Raw/partially cooked Molluscan Shellfish vs Fish (all fish, crustaceans, etc., excluding the estimated 0.1% shellfish consumed raw/partially cooked):

   Compared on a pound for pound consumed basis:

   Raw/partially cooked molluscan shellfish are 18,430 times more likely to make you ill than fish

   Raw/partially cooked molluscan shellfish are 21,000 times more likely to result in death than fish

PLACING THINGS IN PERSPECTIVE

The following values are estimates of the risk of disease from a 4 ounce serving of the specified commodity:

1. Chicken: About one illness episode will occur per 25,000 servings

2. All Seafood (including raw/partially cooked molluscan shellfish):

   About 1 illness episode will occur per 250,000 servings

3. Fish (all varieties, 99.9+% consumed annually, excluding raw/partially cooked molluscan shellfish:

   About 1 illness episode will occur per 5,000,000 servings

4. Raw/partially cooked molluscan shellfish:

   About 1 illness episode will occur per 250 servings (of 4 ounces)

Conclusions: It should be noted that even relatively large errors in the base estimates in the frequency of occurrence of individual diseases or percents of disease attributable to a specific commodity would not have a major impact on the relative risk or rank order of risk.

One must also consider the TOTAL impact of the specific diseases. For example, Norwalk agent causes the bulk of raw shellfish-associated disease, but is a mild, short-lived illness, with no attributable mortality. *V. vulnificus* contributes virtually all risk of disease from raw shellfish, but deaths are almost exclusively limited to persons with cirrhosis. In contrast, salmonellosis and campylobacteriosis cause acute gastrointestinal disease in nearly all persons, and the disease can last from 1 to 7 days or more. *Campylobacter* and *Salmonella* can trigger unpleasant, serious, long-lasting sequelae, and cause death in a broader spectrum of individuals.

CONCLUDING COMMENT:

The above risk analysis was limited to chicken because the most complete data on associated sporadic illness is available for that commodity along with the necessary consumption data. It is NOT intended as an indictment of chicken or any other commodity. Disease episodes caused by chicken are generally avoidable at the consumer level with careful handling and adequate cooking. No one doubts that the associated burden of potentially harmful microorganisms should be lowered, and great efforts are being made to do so.

In stratifying public health priorities, the TOTAL risk must be examined. Total risk not only includes numerical incidence, but severity, potential mortality, chronic results, etc. For example, it is estimated that 20,000 cases of infection with *E. coli* O157:H7 may occur annually. Most of these may be associated with ground beef. Assuming one-third of beef is consumed as ground beef (5.5 billion pounds), then 3636 cases per billion pounds would be the result. This would suggest that this disease, in terms of cases of illness per weight of product consumed was less risky than all seafood or chicken.

In a total public health sense however, this one bacterium causes a clinical spectrum of illness from watery diarrhea to bloody diarrhea, and chronic sequelae such as hemolytic uremic syndrome (HUS) and thrombotic thrombocytopenic purpura (TTP). HUS is thought to be the leading cause of acute renal failure in children and can lead to permanent loss kidney function. TTP has a very high (>50%) mortality rate in elderly individuals. Also, the estimated number of deaths associated with E. coli O157:H7 is 415 annually, or 75 per billion pounds of ground beef consumed (if all of this disease is in fact attributable to ground beef). Thus, in terms of number of individual cases of illness, it would seem a fairly low priority, but in terms of impact, this pathogen is a high public health priority. It has not yet been associated with seafood, but that may not reflect its absence, but our inability to cultivate the organism from marine environments.

There may be specific diseases associated with specific foods which are as yet unknown. For example, no cases of listeriosis have been epidemiologically associated with seafoods, yet we find a good deal of Listeria contaminated seafood. There may be a connection made in the future and this would greatly increase the relative risk of seafood.

It is important to remember that we are forced to work with estimates. If more accurate figures are desirable, and in terms of prioritizing public health initiatives they are, then there is a clear need for better surveillance. This does not have to be a nationwide system. Great success in determining the true incidence of listeriosis in the U.S. was made by enacting prospective, active surveillance in geographic regions representative of the U.S. The use of such "sentinel" surveillance would greatly improve the accuracy of estimates and enable true comparisons of risk to be made.

Prepared by: Dr. Douglas Archer, Center for Food Safety and Applied Nutrition
June 9, 1989

SUBMISSION FOR THE RECORD

COMMITTEE ON MERCHANT MARINE AND FISHERIES
SUBCOMMITTEE ON FISHERIES AND WILDLIFE CONSERVATION
AND THE ENVIRONMENT
HOUSE OF REPRESENTATIVES
JUNE 7, 1989

SUBMISSION: Copy of graph depicting contaminants and what types of inspections must be conducted to identify them.

Inspection Methods for Fishery Products

Contaminant Type	Health Hazard	Visual	Organo-leptic	Specific Laboratory Analysis
Bacterial	None to Fatal	NO	NO	YES
Viral	Mild - Moderate	NO	NO	YES
Industrial chemical	?	NO	NO	YES
Pesticide	?	NO	NO	YES
Decomposition	None to Mild	YES/NO	YES	YES
Filth	None	YES	NO	YES/NO
Natural Toxin	Mild to Fatal	NO	NO	YES
Parasites	None to Mild	YES/NO	NO	YES

NO ▪ Not Effective Means
YES ▪ Effective Means

SUBMISSION FOR THE RECORD

COMMITTEE ON MERCHANT MARINE AND FISHERIES
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AND THE ENVIRONMENT
HOUSE OF REPRESENTATIVES
JUNE 7, 1989

SUBMISSION: Copies of Memorandum of Understanding with foreign countries regarding shellfish and MOU's with other agencies regarding research programs for fishery products.

Memorandum of Understanding with foreign countries
There are currently 259 foreign certified shellfish shippers representing four of the eight foreign countries that have signed MOU's with FDA.

1. Australia (3)
2. Canada (208)
3. Mexico (0)
4. New Zealand (38)
5. Republic of Korea (5)
6. England (0)
7. Iceland (0)
8 Japan (0)

FDA and NOAA Fisheries have a Memorandum of Understanding to share research responsibilities for fishery products.

SUBJECT: MOU with the Export Inspection Service, Department of Primary Industry, Australia Concerning Fresh Frozen Molluscan Shellfish (FDA 225-86-2001)

MEMORANDUM OF UNDERSTANDING

Between The

FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH
AND HUMAN SERVICES, UNITED STATES OF AMERICA

And The

EXPORT INSPECTION SERVICE,
DEPARTMENT OF PRIMARY INDUSTRY, AUSTRALIA

CONCERNING THE SANITARY CONTROL OF FRESH FROZEN MOLLUSCAN SHELLFISH
DESTINED FOR EXPORTATION FROM AUSTRALIA TO THE UNITED STATES

I. PURPOSE

The Food and Drug Administration (FDA) and the Department of Primary Industry (DPI) affirm by this memorandum their intention to cooperate in seeking to assure that fresh frozen molluscan shellfish exported from Australia and offered for import into the United States of America (U.S.) are safe and wholesome and have been harvested, processed, transported, and labeled in accordance with the provisions of the National Shellfish Sanitation Program (NSSP) and the requirements of the U.S. Federal Food, Drug, and Cosmetic Act, the U.S. Public Health Service Act, the U.S. Fair Packaging and Labeling Act, and the Australian Export Control Act. This memorandum defines the sanitation practices and administrative controls and describes the responsibilities of FDA and DPI in implementing these practices and controls. By this document, under the NSSP, FDA officially recognizes DPI as the authority for certifying shellfish shippers intending to export fresh frozen shellfish from Australia to the United States.

II. BACKGROUND

The sanitary control of shellfish in interstate commerce in the United States is administered by FDA in cooperation with the American States under the NSSP. The NSSP provides the States and industry with a mechanism by which shellfish dealers can be "certified" as shipping shellfish that have been harvested, handled, and processed in conformity with the sanitation and administrative guidelines of the NSSP. In most instances, food control authorities rely on the integrity of the NSSP certification controls to determine the acceptability of the shellfish product.

FDA, the States, and many foreign control authorities recognize the substantial benefit that can result from the use of a similar procedure for imported shellfish. Therefore, it is FDA's policy to enter into memoranda of understanding with foreign control authorities willing to apply the sanitation and administrative controls of the NSSP to exported lots of shellfish that are to be offered for import to the United States. These agreements permit the foreign control authorities to certify foreign processors and shippers of fresh frozen shellfish and to have these dealers listed on FDA's "Interstate Certified Shellfish Shippers List" (ICSSL). FDA and American State authorities, in turn, will recognize these shipments as being certified under the NSSP.

Certification of foreign shellfish dealers exporting to the United States is normally limited to those dealers shipping fresh frozen products. This limitation is based on fishery conservation concerns over the possible introduction of exotic infectious organisms into U.S. fishery stocks from foreign fishery stocks. The processing and freezing of shellfish substantially reduce the possibility that such introductions will occur.

The sanitary control of shellfish in Australia is administered by DPI in cooperation with Australian State control agencies. DPI has authority under the Australian Export Control Act of 1982 to inspect shellfish processors preparing products for export, to set quality standards, and to certify compliance of export lots with these standards. Australian State public health and fishery authorities have jurisdiction under various Australian Federal and State public health and fishery regulations to survey and classify shellfish growing areas and to control harvesting and shipping operations. Laboratory support is provided by private laboratories under agreements with Australian Federal and State authorities.

III. SUBSTANCE OF AGREEMENT

A. DEFINITIONS

1. Advisory agencies. Advisory agencies are the Australian Government Analytical Laboratories or other laboratories accredited by the Australian National Association of Testing Authorities that provide analytical support to shellfish control authorities associated with this memorandum.

2. Central file. Central file is the location where each shellfish sanitation authority stores and maintains program information, data, and reports.

3. Enforcement agencies. Enforcement agencies are the Department of Primary Industry (DPI) and the Australian State enforcement agencies having regulatory authority over the production, harvesting, processing, transport, classification, and export of certified shellfish to the United States under the terms of this memorandum.

4. Lot. A lot is a collection of primary containers or units of the same size, type, and style, produced under conditions as nearly uniform as possible, designated by a common container code or marking, and in any event, containing no more than a day's production.

5. Shellfish. Shellfish are edible species of oysters; clams, including cockles; and mussels.

6. State enforcement agencies. State enforcement agencies are the Australian State departments that have regulatory authority over the production, harvesting, transport, and processing of shellfish and the classification, monitoring, and control of harvest areas, and that have entered into an agreement with DPI for the purposes of this memorandum.

B. DPI RESPONSIBILITIES

DPI will:

1. Develop and maintain interagency agreements and protocols with Australian State enforcement agencies to coordinate Australian Federal and State implementation of NSSP controls, as necessary.

2. Maintain NSSP required legal, administrative, and sanitation controls over shellfish exported by certified Australian dealers by ensuring that Australian State enforcement agencies:

(a) Classify shellfish harvesting areas based upon comprehensive sanitation surveys;

(b) Prepare sanitation survey reports and maintain survey data in a central file;

(c) Update survey data annually and periodically review the classification status of each harvest area;

(d) License and supervise harvesting and relaying operations and provide proper source labeling for shellstock;

(e) Restrict harvesting of shellfish from unapproved areas and take appropriate enforcement action against violators; and

(f) Evaluate laboratory practices at least annually and encourage participation in FDA's voluntary quality assurance programs.

3. Inspect firms processing fresh frozen shellfish for export to ensure compliance with NSSP controls.

4. Certify dealers exporting fresh frozen shellfish that comply with NSSP requirements on an annual basis and notify FDA of the name, location, and certification number of those firms on Form FD-3038B, "Shellfish Certification."

5. Cancel the certificate of any firm operating out of compliance with the requirements of the NSSP, utilizing shellfish from nonapproved areas, or shipping shellfish that do not conform to the requirements of the U.S. Federal Food, Drug, and Cosmetic Act and the U.S. Public Health Service Act.

6. Ensure that all containers of each lot of fresh frozen shellfish certified for export are identified with the shipper's address, certification number, and lot number or code, together with all other information required by the U.S. Federal Food, Drug and Cosmetic Act, the U.S. Public Health Service Act, and the U.S. Fair Packaging and Labeling Act.

7. Maintain a central file of program records including but not necessarily limited to sanitation survey reports, inspection reports, laboratory evaluation reports, and enforcement actions. These records are made available to FDA for review upon request.

8. Provide inspection results, as appropriate, and other program information, including FDA evaluation reports, interpretations, and laboratory quality assurance program information, to Australian State enforcement and advisory agencies.

9. Review periodically, but at least annually before recertification, the level of conformity to NSSP requirements that is being enforced by DPI and the Australian State enforcement and advisory agencies and provide a report of the review to FDA as necessary, or at least annually.

10. Provide FDA with information about current or potential new public health problems affecting shellfish intended for export to the United States.

11. Make travel arrangements in Australia for, and conduct joint inspections with, FDA evaluation officers at FDA's request. Meet transportation expenses in Australia of FDA officials making inspections in accordance with this memorandum.

C. FDA RESPONSIBILITIES

FDA will:

1. Recognize Australia as a participant in the NSSP with full rights to participate in national workshops, cooperative research programs, seminars, training courses, and other NSSP activities; to make recommendations for changes or improvements in the procedures, methods, standards, and guidelines of the NSSP; and to have DPI certify Australian dealers for inclusion in FDA's ICSSL.

2. Publish the names, locations, and certification numbers of Australian shellfish shippers certified by DPI in the monthly publication of the ICSSL upon receipt of Form FD-3038B.

3. Provide limited training and technical assistance to enforcement agency personnel in shellfish sanitation program administration, laboratory procedures, and growing area classification procedures upon request of DPI and subject to availability of funds for such purposes.

4. Inform DPI of the reasons for any FDA detentions of certified frozen shellfish shipments from Australia. Additional information that FDA will provide shall include, but not necessarily be limited to:

(a) Commodity identification;
(b) Commodity code, lot, and certification number:
(c) Name and address of the shipper;
(d) Sampling procedure;
(e) Methods of analysis and confirmation; and
(f) Administrative guidelines.

5. Advise DPI of any questions that FDA has received from U.S. food control officials concerning the safety or wholesomeness of frozen shellfish imported into the United States from Australia. Upon receiving such questions, FDA will seek to determine the reason for the problems and will inform DPI of any action taken under American State and local laws or regulations with regard to such frozen shellfish imports.

6. Participate with DPI in joint evaluations of the Australian shellfish sanitation program as it pertains to certifying dealers. Joint evaluations normally will be conducted at 2-year intervals to ascertain Australia's level of conformity with the requirements of the NSSP and the responsibilities specified in this memorandum. FDA will pay round trip transportation expenses between the United States and Australia and the per diem of the members of the FDA evaluation team while in Australia.

7. Facilitate the exchange of information between DPI and U.S. Federal and State agencies concerned with the introduction and proliferation of exotic infectious organisms that might be carried by Australian shellfish.

D. SHARED RESPONSIBILITIES

DPI and FDA will:

1. Exchange information through nominated liaison officers concerning significant proposed and final changes in program operations and procedures including:

(a) Methods and procedures for sampling;
(b) Methods of analysis;
(c) Methods of confirmation;
(d) Administrative guidelines, tolerances, specification standards, and nomenclature;
(e) Reference standards; and
(f) Inspection procedures.

Final changes will be considered incorporated into the appropriate provisions of this memorandum 90 days after receipt unless written objection is provided to the other party.

2. Provide written notification to the other party of any changes in liaison officers. Changing liaison officers will not otherwise constitute a change in the provisions of this memorandum.

E. REFERENCES

1. U.S. Department of Health and Human Services (formerly U.S. Department of Health, Education, and Welfare), PHS, National Shellfish Sanitation Program, Manual of Operations: Part I Sanitation of Shellfish Growing Areas, 1965 Revision; Part II Sanitation of the Harvesting and Processing of Shellfish, 1965 Revision; Part III Public Health Service Appraisal of State Shellfish Sanitation Programs, 1965 Revision, PHS Publication No. 33.

2. Association of Official Analytical Chemists, Official Methods of Analysis, 14th Ed., Association of Official Analytical Chemists, Inc., 1111 North 19th St., Suite 210, Arlington, VA 22209, U.S.A., 1984.

3. Food and Drug Administration, "Interstate Certified Shellfish Shippers List," published monthly and distributed to food control officials and other interested persons by FDA, Center for Food Safety and Applied Nutrition, Shellfish Sanitation Branch (HFF-344), 200 C St., SW., Washington, DC 20204.

4. Federal Food, Drug, and Cosmetic Act, 1938, as amended, U.S. Code, Title 21.

5. Public Health Service Act, as amended, U.S. Code, Title 42.

6. Fair Packaging and Labeling Act, Public Law 89-755, approved November 3, 1966.

7. American Public Health Association, Recommended Procedures for the Examination of Seawater and Shellfish, 4th Ed., 1970, APHA, Inc., 1015 15th St. NW., Washington, DC 20036.

8. Food and Drug Administration, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food," regulations, 21 CFR Part 110.

9. Food and Drug Administration, "Definitions and Standards for Food," "Fish and Shellfish" regulations, 21 CFR Part 161.

10. Food and Drug Administration, "Specific Administrative Decisions Regarding Interstate Shipments," "Shellfish," 21 CFR 1240.60.

11. Food and Drug Administration, "Food Service Sanitation on Land and Air Conveyances, and Vessels," "Special Food Requirements," 21 CFR 1250.26.

12. Export Control Act, 1982.

13. Prescribed Goods (Orders) Regulations.

14. Prescribed Goods (General) Orders.

15. Fish Orders.

IV. PARTICIPATING PARTIES

A. Export Inspection Service,
Department of Primary Industry,
Edmund Barton Bldg.,
Canberra ACT 2600,
AUSTRALIA.

B. Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
U.S.A.

V. LIAISON OFFICERS

A. For Department of Primary Industry:

Director (Fish Export Standards),
(currently David Walter),
Export Inspection Service,
Department of Primary Industry,
Canberra ACT 2600,
Australia,
Telephone: 062-725399,
Telex: 62188.

B. For Food and Drug Administration:

Chief, Shellfish Sanitation Branch,
(currently J. David Clem),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
200 C St. SW.,
Washington, DC 20204,
202-485-0149.

VI. PERIOD OF AGREEMENT

This agreement will become effective upon acceptance by both parties and will remain in effect indefinitely. It may be modified by mutual consent or terminated by either party upon a 30-day advance written notice to the other.

APPROVED AND ACCEPTED FOR THE
DEPARTMENT OF PRIMARY INDUSTRY
OF AUSTRALIA

By: P. H. [illegible]

Title: Director, Export Inspection Service

Date: Sixth of June 1986.

APPROVED AND ACCEPTED FOR THE
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN
SERVICES, UNITED STATES OF AMERICA

By: John M Taylor

Title: Acting Associate Commissioner for Regulatory Affairs

Date: September 12, 1986

SUBJECT: Agreement with CANADA on Sanitary Control of Shellfish Industry (FDA-225-75-2021)

ANNEX

MEMORANDUM OF AGREEMENT

Between

THE UNITED STATES OF AMERICA

And

CANADA

"In order to improve the sanitary practices prevailing the shellfish industries of Canada and the United States, it is agreed as follows:

"1. Whatever manual of recommended practice for sanitary control of the shellfish industry is approved by both the United States Public Health Service and the Canadian Department of National Health and Welfare, will be regarded as setting forth the sanitary principles that will govern the certification of shellfish shippers.

"2. The degree of compliance with those principles obtained by the State authorities of the United States will be reported to the Canadian Department of National Health and Welfare by the United States Public Health Service, and the degree of compliance obtained by the Provincial and other competent authorities in Canada will be reported by the Canadian Department of National Health and Welfare to the United States Public Health Service.

"3. Whenever inspections of shellfish handling facilities or of shellfish growing areas are desired by either party to this Agreement, the other party will endeavor to facilitate such inspections.

"4. This Agreement may be terminated by either party giving thirty days' notice."

"The Secretary of State presents his compliments to His Excellency the Ambassador of Canada and has the honor to refer to his note No. 106 of March 4, 1948 proposing that an agreement be entered into between the Governments of the United States of America and Canada in the following terms:

MEMORANDUM OF AGREEMENT (see above)

"The Memorandum of Agreement as set forth above is acceptable to the Government of the United States of America. As proposed in His Excellency's note, therefore, that note and the present reply are regarded as constituting an agreement between the two Governments, effective on the date of the present note.

"Department of State,
"Washington, April 30, 1948."

****

"No. 106

"The Canadian Ambassador presents his compliments to the Secretary of State and, on the instructions of his Government, has the honour to inform him that in order to improve sanitary practices in the shellfish industries of Canada and the United States and to facilitate the exchange of information with reference to endorsement of shellfish certifications, the Canadian Department of National Health and Welfare and the United States Public Health Service have agreed on the desirability of an Agreement being concluded on the points and in the terms set forth in the annexed memorandum.

"If such an agreement is acceptable to the United States Government, it is the proposal of the Canadian Government that this Note and its Annex together with a reply agreeing thereto, constitute an Agreement between the two Governments effective from the date of the reply from the United States authorities.

"Canadian Embassy,
Washington, D.C.
"4th March 1948.

SUBJECT: MOU with Mexico regarding Fresh and Fresh Frozen Oysters, Clams, and Mussels (FDA 225-79-4009)

MEMORANDUM OF UNDERSTANDING TO CONTROL THE SANITARY QUALITY OF FRESH OR FRESH FROZEN BIVALVE MOLLUSCA DESTINED FOR EXPORTATION TO THE UNITED STATES OF AMERICA

Between The

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
UNITED STATES OF AMERICA

And The

SECRETARIAT OF HEALTH AND WELFARE
OF THE
UNITED STATES OF MEXICO

The Secretariat of Health and Welfare of the United States of Mexico (SSA) and the Food and Drug Administration (FDA) of the Department of Health, Education and Welfare of the United States of America affirm by this document their intention to cooperate in assuring that fresh and fresh frozen oysters, clams and mussels exported to the United States of America are safe, wholesome and have been harvested, transported, processed and labeled in accordance with the provisions of the National Shellfish Sanitation Program (NSSP) and requirements of the Federal Food, Drug and Cosmetic Act of the United States of America.

I. TERMS:

For purposes of this Memorandum, both parties agree to the following definitions:

Lot - A number of shellfish from no more than one day's harvest, from a single growing area, produced under conditions as nearly uniform as possible, placed in a collection of primary containers or units of the same size, type and style, and identified by a common container code or marking.

Central file - The location where shellfish control program information, data, and reports are stored and maintained.

Shellfish - All edible species of molluscan bivalves except scallop species from the family Pectinidae. Only shellfish that are offered for entry into the United States of America as fresh or fresh frozen products are covered under this Memorandum of Understanding.

Marine biotoxins - Natural toxins produced by marine dinoflagellates such as *Gonyaulax catenella*, *Gonyaulax tamarensis*, and *Gymnodinium breve* and concentrated by shellfish during the feeding process.

II. FOOD AND DRUG ADMINISTRATION AND THE SECRETARIAT OF HEALTH AND WELFARE

A. Both parties agree to provide information concerning proposed changes in the following:

1. Methods and procedures for sampling.
2. Methods of analysis.
3. Methods of confirmation.
4. Administrative guidelines, tolerances, specification standards and nomenclature.
5. Reference standards.
6. Inspectional procedures.

B. Both parties agree to inform each other on a timely basis of the fundamentals of the following:

1. Proposed modification of existing Federal or local regulations.
2. Proposed new Federal regulations.
3. Proposed new legislation.
4. Proposed modifications to the national shellfish sanitation programs.

C. Both parties agree to name a liaison officer who will coordinate all operational matters relating to this Memorandum. The liaison officers will be responsible for facilitating exchanges of information and expeditiously informing other interested parties within their respective countries on shellfish control problems requiring prompt attention. Each party agrees to provide notification of any changes in liaison officer appointments. Such notification shall constitute a formality and does not require a revision of this agreement.

The Secretariat of Health and Welfare liaison officer is the C. Director General de Coordinacion y Control Ambiental.

The Food and Drug Administration liaison officer is the Director, Mexican Liaison Staff.

D. Both parties agree that the language used for the documents which are interchanged within this Memorandum is that of the country of origin, accompanied by a first (rough) draft translation in the language of the country to which it is destined.

III. THE SECRETARIAT OF HEALTH AND WELFARE AGREES TO:

A. Classify its shellfish harvesting waters in accordance with the procedures and standards set forth in the NSSP.

B. Assure that only shellfish harvested from areas which meet NSSP approved water quality and marine biotoxin standards and processed according to NSSP guidelines will be exported to the United States of America.

C. Inspect the harvesting, transporting and processing of shellfish at sufficient frequency to assure compliance with NSSP sanitary control practices.

D. Issue sanitation quality certificates for harvesting areas, only to those shellfish exporting firms and cooperatives that comply with NSSP recommended practices and to notify FDA of the name, location and certification number of these firms or cooperatives on Form FD-3038b "Shellfish Certification". To cancel a firm's certification, the SSA will send a completed Form FD-3038c "Certification Cancellation" to FDA.

E. Require that all containers or units of all lots of shellfish exported to the United States of America be identified by lot number and certification number, together with all other information required by the U.S. Federal Food, Drug and Cosmetic Act.

F. Invite technical observers of the FDA to visit the firms or cooperatives which have certificates, as well as the shellfish growing areas. Such visits will be made on an annual basis or at a frequency deemed appropriate by both parties to observe the operation of the Mexican Bivalve Mollusca Sanitation Program.

G. Make travel arrangements for the FDA technical observers and provide the necessary facilities for carrying out their observations within Mexico.

H. Participate in FDA's laboratory quality assurance programs.

These include:

1. Participation in the analysis of split samples of:

   a. Seawater or shellfish meats to determine indicator bacteria or pathogens.

   b. Shellfish meats to determine heavy metals and other chemical or radionuclide substances as may be deemed necessary.

2. The evaluation of new methods and procedures, including reagents, media, or other materials as well as instruments and equipment performance.

I. The establishment of a central office that will maintain a central file of laboratory results, including routine monitoring data and data from quality assurance programs. Standard formats for collecting and reporting data should be used and these will be printed in English and Spanish.

J. Promulgation and enforcement of sanitation laws and regulations governing the growing, harvesting, processing and shipment of shellfish to the United States of America are the sole responsibility of the SSA.

IV. FOOD AND DRUG ADMINISTRATION (FDA) AGREES TO:

A. Publish the names, locations and certification numbers of firms or cooperatives submitted by the SSA. These will appear in the monthly INTERSTATE CERTIFIED SHELLFISH SHIPPERS LIST.

B. Upon request of the SSA, the FDA will provide training to technical personnel on administrative procedures, inspection and laboratory procedures, and classification of shellfish growing areas.

C. Whenever shellfish are detained by FDA due to noncompliance with recommended NSSP practices, FDA will inform SSA of the reason or reasons for the detention.

This information includes:

1. Commodity, lot and certification number.
2. Name and address of the shipper.
3. Reason for the detention.
4. Sampling procedure.
5. Methods of analysis and confirmation.
6. Administrative procedures.

D. FDA agrees to make travel arrangements for, and pay round trip transportation expenses of, its observation team between the United States of America and Mexico. FDA will also pay all per diem of the observation team.

V. NATIONAL SHELLFISH SANITATION PROGRAM (NSSP) OF THE UNITED STATES OF AMERICA.

The SSA may participate in workshops of the United States of America, cooperative research programs, seminars, training courses and other activities designed for the timely interchange of technical information, assistance and joint resolution of problems confronting the NSSP. The SSA may participate in a joint evaluation of the United States of America's imports from Mexico. The SSA may also:

A. Make recommendations for changes and improvements in NSSP procedures, methods and standards.

B. Be advised by FDA in case of questions by state or local food control officials regarding the certification, safety and wholesomeness of shellfish imported from Mexico. FDA will, if so requested, seek to determine the reason for the problem and inform the SSA of any action taken relative to United States of America state and local laws governing such shellfish imports.

This document will become effective on the date it is signed by both parties and shall remain in effect until one of the parties gives 60 days notice to the other of its intention to terminate or modify it.

In witness whereof, both parties sign this Memorandum of Understanding in the City of Mexico, on the 7th day of the month of March of 1979.

For the SSA, Mexico

Ing. Humberto Romero Alvarez
Subsecretario de Mejoramiento
del Ambiente

For the FDA, United
States of America

Sherwin Gardner
Deputy Commissioner

Dr. Ramon Alvarez Gutiérrez
Director General de Asuntos
Internacionales.

SUBJECT: MOU with New Zealand regarding exportation of fresh and fresh frozen shellfish to the US (FDA 225-81-2000)

MEMORANDUM OF UNDERSTANDING

Between The

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

UNITED STATES OF AMERICA

And The

MINISTRY OF AGRICULTURE AND FISHERIES

GOVERNMENT OF NEW ZEALAND

I. PURPOSE

The purpose of this MOU is to officially recognize the New Zealand Ministry of Agriculture and Fisheries (MAF) as the certifying authority for New Zealand shellfish shippers of fresh and fresh frozen shellfish imports destined for the U.S. market. This document also defines terms and describes the responsibilities of the MAF and FDA in the operation and management of the term of this MOU in accordance with operational guidelines of the National Shellfish Sanitation Program (NSSP).

The New Zealand Ministry of Agriculture and Fisheries (MAF) and the Food and Drug Administration (FDA) of the Department of Health and Human Services of the United States of America affirm by this document their intention to cooperate in assuring that fresh and fresh frozen molluscan bivalves exported to the United States are safe, wholesome, and have been harvested, transported, processed and labeled in accordance with the provisions of the National Shellfish Sanitation Program (NSSP) and requirements of the Federal Food, Drug, and Cosmetic Act.

II. BACKGROUND

Early in the last decade, the New Zealand Department of Marine initiated a shellfish culture program to augment natural production of two commercial species of shellfish, Perna canaliculus (greenlipped mussel) and Crassostrea glomerata (rock oyster).

Responsibilities for fishery development in New Zealand were transferred from the Department of Marine to the MAF in 1973. The MAF, in conjuction with the Department of Health and other agencies, has continued to develop a shellfish control program which could meet or exceed the recommendations of the NSSP. The New Zealand shellfish industry's interest in U.S. shellfish markets resulted in an MAF request for a shellfish evaluation mission in July 1979.

In response to this request, an evaluation of the New Zealand shellfish control program was conducted by a two-person FDA mission in November, 1979. The mission concluded that the New Zealand shellfish control program conforms, in general, to the guidelines of the NSSP and the Federal Food, Drug, and Cosmetic Act. In its final report to the MAF, the mission recommended that the FDA accept the New Zealand program through an MOU with the MAF.

III. SUBSTANCE OF AGREEMENT

A. Terms

For purposes of this Memorandum, both parties agree to the following definitions:

1. Lot. A collection of primary containers or units of the same size, type, and style, produced under conditions as nearly uniform as possible, designated by a common container code or marking, and in any event, no more than a day's production.
2. Central File. The single location where shellfish control program information, data, and reports are stored and maintained.
3. Bait Shellfish. Shucked shellfish labeled and intended for bait use only; not for human consumption.
4. Shellfish. All edible species of molluscan bivalves except

scallop species from the family Pectinidae. Only molluscan bivalves that are offered for entry into the United States as fresh or fresh frozen products are intended for coverage under this Memorandum of Understanding.

5. *Marine Biotoxins*. Natural toxins produced by marine dinoflagellates such as *Gonyaulax catenella*, *Gonyaulax tamarensis*, and *Gymonodinium breve* and concentrated by shellfish during the feeding process.

B. Information Exchange

Both parties agree to provide information concerning proposed changes in the following:

1. Methods and procedures for sampling.
2. Methods of analysis.
3. Methods of confirmation.
4. Administrative guidelines, tolerances, specification standards, and nomenclature.
5. Reference standards.
6. Inspectional procedures.
7. Proposed modification of existing Federal or local regulations.
8. Proposed new Federal regulations.
9. Proposed new legislation.
10. Proposed modifications to the National Shellfish Sanitation Program.

C. MAF Responsibilities

1. The MAF agrees to classify its shellfish harvesting waters in accordance with the procedures and standards set forth in the NSSP Manual of Operations. The MAF will assure that only fresh and fresh frozen shellfish harvested from areas which meet NSSP approved water quality and marine biotoxin standards and processed

according to NSSP guidelines will be exported to the United States.

2. The MAF agrees to inspect harvesting, transporting, and processing operations of fresh and fresh frozen shellfish at sufficient frequency to assure compliance with NSSP sanitary control practices.

3. The MAF agrees to issue certifications only to those fresh and fresh frozen shellfish shipping firms that comply with NSSP recommended practices and to notify FDA of the name, location, and certification number of those firms on Form FD-3038b "Shellfish Certification." To cancel a firm's certification, the MAF will send to FDA a completed Form FD-3038c "Certification Cancellation."

4. The MAF agrees to require all containers of all lots of fresh and fresh frozen shellfish exported to the United States to be identified by lot number and certification number, together with all other information required by the Federal Food, Drug, and Cosmetic Act and Fair Packaging and Labeling Act.

5. The MAF agrees to facilitate joint FDA-MAF inspections of New Zealand's certified fresh and fresh frozen shellfish processing firms, approved growing waters and related harvesting and handling practices. Such inspections will be made on an annual basis or at a frequency deemed appropriate to determine that the MAF shellfish sanitation control program is equivalent to NSSP recommended practices and that only safe and wholesome fresh and fresh frozen shellfish are exported to the United States.

6. The MAF agrees to make travel arrangements for, and pay transportation expenses of, the FDA inspection team while the team is conducting inspections within New Zealand.

7. The MAF agrees to participate to the maximum extent possible in FDA's laboratory quality assurance programs. These may include:

   a. Participation in the analysis of split samples of:

      (i) Seawater or shellfish meats for indicator bacteria or pathogens.

      (ii) Shellfish meats for heavy metals or other chemical or radionuclide contaminants as may be necessary.

b. The evaluation of new methods and procedures including reagents, media, or other materials and instruments, and equipment performance.

8. The MAF agrees to the establishment of a central office within New Zealand to collate and maintain a central file of laboratory results, including routine monitoring data and data from quality assurance programs. Standard formats for collecting and reporting data will be used.

9. MAF agrees to assure that if lots of shellfish are imported into the United States for use as bait, each container will be labeled, "Not for human use", and the contents will be decharacterized by use of a permanent colored dye.

10. MAF agrees that the delegation of responsibilities for shell fish control in New Zealand is as given below:

a. Promulgation and enforcement of regulations governing the growing, harvesting, processing, and shipment of fresh or fresh frozen shellfish produced by New Zealand for export to the United States is the sole responsibility of the MAF.

b. The principal government agency in the New Zealand shellfish program is the Ministry of Agriculture and Fisheries, with two divisions of the Ministry being directly involved: the Fisheries Management Division and the Meat Division. The responsibilities of the two divisions are set out in a Cooperative Agreement. Meat Division has the overall responsibility for coordination and administration of the New Zealand program.

c. The Public Health Division of the New Zealand Department of Health has direct involvement in the program. Its functions are the classification and continual monitoring of shellfish growing waters as stated in the Memorandum of Understanding between the Ministry of Agriculture and Fisheries and the Department of Health.

d. Laboratory analysis is carried out by Public Health Laboratories of the Department of Health and the Chemistry Division of the Department of Scientific and Industrial Research (DSIR).

e. Research related to the shellfish industry is conducted by Fisheries, the DSIR Fish Processing Unit and Massey University Fish Research Unit.

f. Liaison is maintained with the Fishing Industry Board and the Regional Water Boards.

D. FDA Responsibility

1. FDA agrees to publish the names, locations and certification numbers of certified firms submitted by the MAF. These firms will appear in the monthly INTERSTATE CERTIFIED SHELLFISH SHIPPERS LIST.

2. Upon request FDA will provide limited training to technical personnel in laboratory procedures, classification of shellfish growing areas, plant inspection and administrative procedures subject to availability of funds for such purposes.

3. Whenever New Zealand shellfish are detained by FDA due to noncompliance with NSSP agreed upon practices or applicable laws or regulations, FDA will inform MAF of the reason or reasons for the detention. This information will include:

   a. Commodity lot and certification number.

   b. Name and address of the shipper.

   c. Reason for the detention.

   d. Sampling procedure.

   e. Methods of analysis and confirmation.

   f. Administrative guidelines.

4. FDA agrees to make travel arrangements for, and pay round trip transportation expenses of, its inspection team between the United States and New Zealand. FDA will also pay all per diem of the inspection team.

E. National Shellfish Sanitation Program

Upon signing this agreement, the MAF becomes an active participating member of the NSSP. As a full member of the NSSP, the MAF may participate in national workshops, cooperative research programs, seminars, training courses, and other activities designed for the timely exchange of technical information, and provide assistance in the joint resolution of problems confronting the NSSP. The MAF may also:

1. Participate in a joint evaluation of the United States program as it pertains to shellfish exports to New Zealand.
2. Make recommendations for changes and improvements in NSSP guidelines, methods, and standards.
3. Be advised by FDA in the event a State or local food control official questions the certification, safety, or wholesomeness of New Zealand's imported shellfish. FDA will, if so informed, seek to determine the reason for the problem and inform the MAF of any action taken relative to State and local laws or regulations governing such shellfish imports.

REFERENCES

1. US Department of Health and Human Services, Public Health Service (PHS), National Shellfish Sanitation Program, Manual of Operations: Part I Sanitation of Shellfish Growing Areas, 1965 Revision; Part II Sanitation of the Harvesting and Processing of Shellfish, 1965 Revision; Part III Public Health Service Appraisal of State Shellfish Sanitation Programs, 1965 Revision, PHS Publication No. 33.
2. Official Methods of Analysis, 12th ed., Association of Official Analytical Chemists (AOAC), Box 540, Benjamin Franklin Station, Washington, DC 20044, 1975.
3. Food and Drug Administration, "INTERSTATE CERTIFIED SHELLFISH SHIPPERS LIST," published monthly and distributed to food control officials and other interested persons by FDA, Bureau of Foods, Fishery Technology Branch (HFF-217), 200 C St. SW., Washington, DC 20204.
4. Federal Food, Drug, and Cosmetic Act, United States Code, Title 21.
5. Fair Packaging and Labeling Act, Pub. L. 89-755, approved November 3, 1966.
6. American Public Health Association, "Recommended Procedures for the Examination of Seawater and Shellfish," 4th ed., 1970, APHA, Inc., 1015 18th St. NW., Washington, DC 20036.

7. Food and Drug Administration, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food" regulations, 21 CFR Part 110.

8. Food and Drug Administration, Definitions and Standards for Food, "Fish and Shellfish" regulations 21 CFR Part 161.

9. Cooperative Agreement between the Meat Division and Fisheries Management Division of the Ministry of Agriculture and Fisheries relative to the sanitary control of the shellfish industry.

10. Memorandum of Understanding between Ministry of Agriculture and Fisheries and Department of Health relative to the certification of export shellfish to the United States of America.

IV. NAME AND ADDRESS OF PARTICIPATING AGENCY

Ministry of Agriculture and Fisheries
P.O. Box 2298
Wellington, New Zealand

V. LIAISON OFFICERS

The liaison officer for each party will be responsible for facilitating exchanges of information and expeditiously informing other interested parties within their respective countries on shellfish control problems requiring prompt attention. Each party agrees to provide notification of any changes in liaision officer appointments. Such notificaiton shall constitute an amendment to, and not require a revision of, this agreement.

A. Liaison Officer for MAF:
Mr. Peter Withers, Second Secretary,
New Zealand Embassy,
37 Observatory Circle, NW.,
Washington, DC 20008.

B. Liaison Officer for FDA
Mr. Daniel A. Hunt, Assistant Chief,,
Fishery Technology Branch, Bureau of Foods,
Food and Drug Administration
200 C St. SW.,
Washington, DC 20204.

IV. PERIOD OF AGREEMENT

This agreement when accepted by both parties, will have an effective period of performance from date of signature until terminated by either party. This agreement may be modified by mutual consent of both parties or may be terminated by either party upon a thirty day advance written notice to the other.

APPROVED AND ACCEPTED
FOR THE MINISTRY OF
AGRICULTURE AND FISHERIES:

By: ____________________
Title: Director-General of Agriculture & Fisheries
Country: New Zealand
Date: October 30 1980

APPROVED AND ACCEPTED
FOR THE FOOD AND DRUG
ADMINISTRATION:

By: ____________________
Title: Associate Commissioner for Regulatory Affairs
Country: USA
Date: OCT 14 1980

SUBJECT: MOU with Korea regarding frozen molluscan shellfish for United States consumption

MEMORANDUM OF UNDERSTANDING

between the

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

UNITED STATES OF AMERICA

And The

NATIONAL FISHERIES ADMINISTRATION,
REPUBLIC OF KOREA

CONCERNING THE SANITARY CONTROL OF FRESH FROZEN MOLLUSCAN SHELLFISH DESTINED FOR EXPORTATION FROM KOREA TO THE UNITED STATES

I. PURPOSE

The Food and Drug Administration (FDA) and the National Fisheries Administration (NFA) of the Ministry of Agriculture, Forestry and Fisheries of the Republic of Korea (ROK) affirm by this memorandum their intention to continue the 1972 Shellfish Sanitation Agreement between the Government of the United States of America and the Government of the Republic of Korea. Both governments agree to cooperate in seeking to assure that fresh frozen molluscan shellfish exported from the Republic of Korea and offered for import into the United States are safe and wholesome and have been harvested, processed, transported, and labeled in accordance with the sanitation principles of the National Shellfish Sanitation Program (NSSP) and the requirements of the U.S. Federal Food, Drug and Cosmetic Act, the U.S. Public Health Service Act, the U.S. Fair Packaging and Labeling Act, and the Korean Ministry of Agriculture and Fisheries' Ordinance Number 699. This memorandum defines the sanitation practices and administrative controls and describes the responsibilities of FDA and NFA in implementing these practices and controls.

II. BACKGROUND

Early in its history, the Republic of Korea established a national policy for fisheries development. This policy resulted in the rapid expansion of the oyster industry on the Korean south coast utilizing highly effective hanging culture methods. Given the possibility of exporting shellfish to markets in the United States (U.S.), the ROK promulgated laws and regulations to control the developing fisheries. Notable among these laws was Ministry of Agriculture and Fisheries Ordinance Number 699 which provides the basic legal authority for a Korean shellfish export program.

In 1967, the Korean Government requested technical consultation and advice on the development of an effective oyster production program from the U.S. Public Health Service and the U.S. Fish and Wildlife Service. The U.S. responded by sending a mission composed of public health and fisheries experts to Korea. The mission provided a detailed report with recommendations for developing a shellfish sanitation control program.

In 1970, the Director General of the Korean, Office of Fisheries requested a second mission from the U.S. to evaluate the Korean Shellfish Sanitation Program (KSSP). The Food and Drug Administration sent a two person mission to Korea in September and October 1971. The mission concluded that the Korean program met or exceeded NSSP guidelines and "... that the Korean Government can and will fulfill its responsibilities as a member of the National Shellfish Sanitation Program." On the basis of these conclusions, FDA endorsed the Korean Shellfish Sanitation Program.

On November 24, 1972, the Government of the United States of America signed two fishery agreements with the Government of the Republic of Korea. One concerned cooperation in fisheries in the North Pacific with special reference to the marketing of certain shellfish products. The other agreement applied to export of Korean fresh and frozen molluscan shellfish to the U.S.. The signing of the latter agreement was contingent upon ratification of the fisheries agreement by the U.S. Because the 1971 FDA mission found that the Korean shellfish control program satisfied public health requirements, the U.S. ratified this agreement.

With the ratification of the 1972 Shellfish Sanitation Agreement, FDA officially recognized the ROK Office of Fisheries as the certifying authority for Korean shippers of fresh and fresh-frozen shellfish intended for U.S. markets. In accordance with this agreement, FDA has conducted annual reviews of the Korean Shellfish Sanitation Program and has found a high degree of compliance with NSSP guidelines. In 1980, the name of the ROK fisheries agency was changed from Office of Fisheries to National Fisheries Administration (NFA).

The sanitary control of shellfish in interstate commerce in the U.S. is administered by FDA in cooperation with state agencies under the NSSP. The NSSP provides the states and industry with a mechanism by which shellfish firms can be certified as shipping shellfish that have been harvested, handled, and processed in conformity with the sanitation and administrative guidelines of the NSSP. In most instances, food control authorities rely on the integrity of the NSSP certification controls to determine the acceptability of the shellfish product.

FDA and many foreign control authorities recognize that substantial benefit can result if shellfish that are to be offered for import into the U.S. are harvested, handled, and processed in accordance with the procedures set forth in the NSSP. Therefore, it is FDA's policy to enter into memoranda of understanding with foreign control authorities that are willing to apply the sanitation and administrative controls of the NSSP to lots of shellfish that are intended to be exported and offered for import into the U.S. These agreements permit the foreign control authorities to certify firms and shippers of fresh frozen shellfish and to have these firms and shippers listed on FDA's "Interstate Certified Shellfish Shippers List" (ICSSL). FDA and American state auhorities will recognize shipments so certified as having been certified under the NSSP.

Certification of foreign shellfish dealers exporting to the U.S. is normally limited to those dealers shipping fresh frozen products. This limitation is based on concerns over the possible introduction of exotic infectious organisms into U.S. fishery stocks from foreign fishery stocks. The processing and freezing of shellfish substantially reduce the possibility that such introductions will occur.

III. SUBSTANCE OF AGREEMENT

A. DEFINITIONS

1. Central file. The "central file" is the location where the enforcement agency stores and maintains program information, data, and reports.

2. Enforcement agency. The "enforcement agency" is the National Fisheries Agency, which has regulatory authority in Korea over the production, harvesting, processing, transportation, classification, and export of certified shellfish to the United States under the terms of this memorandum.

3. Lot. A "lot" is a collection of primary containers or units of the same size, type, and style, produced under conditions as nearly uniform as possible, designated by a common container code or marking, and containing no more than a day's production.

4. Marine biotoxins. "Marine biotoxins" are natural toxins produced by dinoflagellates such as *Gonyaulax catenella*, *Gonyaulax tamarensis*, and *Ptychodiscus brevis* and concentrated by shellfish during the feeding process.

5. Shellfish. "Shellfish" are the edible species of oysters; clams; and mussels.

B. NFA RESPONSIBILITIES

NFA will:

1. Maintain the legal, administrative, and sanitation controls over shellfish exported by Korean firms that are required by the NSSP and the KSSP. These controls include:

(a) Classifying shellfish harvesting areas based upon comprehensive sanitation surveys;

(b) Preparing sanitation survey reports and maintaining survey data in a central file;

(c) Updating survey data annually and periodically reviewing the classification status of each harvest area.

(d) Assuring that only shellfish harvested from approved areas that meet NSSP-KSSP approved water quality and marine biotoxin standards are exported to the U.S.;

(e) Evaluating laboratory practices used to test shellfish and seawater at least annually and encouraging participation in FDA's voluntary Quality Assurance Program. The Quality Assurance Program includes examination of standardized laboratory specimens supplied by FDA.

2. Inspect firms processing fresh frozen shellfish for export to the U.S. to ensure compliance with NSSP/KSSP controls.

3. Certify on an annual basis those firms that wish to process and to export fresh frozen shellfish to the U.S. that comply with NSSP/KSSP requirements and notify FDA of the name, location, and certification number of those firms on Form FD-3038B, "Shellfish Certification".

4. Cancel the certificate of any firm that does not comply with the requirements of NSSP/KSSP that obtains shellfish from nonapproved areas, or that ships shellfish that do not conform to appropriate program standards.

5. Ensure that all containers of each lot of fresh frozen shellfish certified for export are identified with the shipping firm's address, certification number, and lot number or code, together with all other information required by the U.S. Federal Food, Drug and Cosmetic Act, the U.S. Public Health Service Act, and U.S. Fair Packaging and Labeling Act.

6. Maintain a central file of program records including but not limited to sanitation survey reports, inspection reports, laboratory evaluation reports, and enforcement actions. NFA will make these records available to FDA upon request.

7. Responsibilities for the management of various components of the KSSP may be delegated to subagencies or administrative units of NFA.

8. Provide FDA with an annual status report describing current or potential new public health problems affecting shellfish intended for export to the U.S. The report should present information on the level of conformity with NSSP requirements enforced by the NFA and a summary of the analysis of water and shellfish data to substantiate new designated area classifications.

9. Make travel arrangements in the Republic of Korea for, and conduct joint inspections with, FDA evaluation officers at FDA's request. Meet transportation expenses in the Republic of Korea of FDA officials making inspections in accordance with this memorandum.

C. FDA RESPONSIBILITIES

FDA will:

1. Recognize the Republic of Korea as a participant in the NSSP with full rights to participate in national workshops, cooperative research programs, seminars, training courses, and other NSSP activities; to make recommendations for changes or improvements in the procedures, methods, standards, and guidelines of the NSSP; and to have NFA certify Korean firms for inclusion in FDA's ICSSL.

2. Publish the names, locations, and certification numbers of Korean shellfish shipping firms certified by NFA in the monthly publication of the ICSSL upon receipt of Form FD-3038B.

3. Provide limited training and technical assistance to enforcement agency personnel in shellfish sanitation program administration, laboratory procedures, and growing area classification procedures upon request of NFA and subject to availability of funds for such purposes.

4. Inform NFA of the reasons for any detentions of certified frozen shellfish shipments from Korea which have been carried out under the authority of the Federal Food, Drug and Cosmetic Act, as amended or Public Health Service (PHS) Act. Additional information that FDA will provide will include, but not necessarily be limited to:

(a) Commodity identification;

(b) Commodity code, lot, and certification number;

(c) Name and address of the shipper;

(d) Sampling procedures;

(e) Methods of analysis and confirmation; and

(f) Administrative guidelines.

5. Participate with NFA in joint evaluations of the shellfish sanitation program as it pertains to certifying firms. Joint evaluations normally will be conducted at two-year intervals to ascertain the level of conformity with the requirements of the NSSP and with the responsibilities specified in this memorandum. FDA will pay round trip transportation expenses between the United States and Korea and the per diem of the members of the FDA evaluation team while in Korea.

6. Facilitate the exchange of information between NFA and U.S. federal and state agencies concerned with the introduction and proliferation of exotic infectious organisms that might be carried by Korean shellfish.

D. SHARED RESPONSIBILITIES

NFA and FDA will:

1. Exchange information through nominated liaison officers concerning significant proposed and final changes in program operations and procedures including:

(a) Methods and procedures for sampling;

(b) Methods of analysis;

(c) Methods of confirmation;

(d) Administrative guidelines, tolerances, specification standards, and nomenclature;

(e) Reference standards; and

(f) Inspection procedures.

2. Provide written notification to the other party of any changes in liaison officers. Changing liaison officers will not otherwise constitute a change in the provisions of this memorandum.

E. OTHER PROVISIONS

The working language for documents exchanged under this memorandum shall be English.

F. REFERENCES

1. U.S. Department of Health and Human Services (formerly U.S. Department of Health, Education, and Welfare), PHS, National Shellfish Sanitation Program, Manual of Operations: Part I Sanitation of Shellfish Growing Areas, 1986 Revision; Part II Sanitation of the Harvesting and Processing of Shellfish, 1965 Revision.

2. Association of Official Analytical Chemists, Official Methods of Analysis, 14th Ed., Association of Official Analytical Chemists, Inc., 111 North 19th Street, Suite 210, Arlington, VA 22209, U.S.A., 1984.

3. Food and Drug Administration, "Interstate Certified Shellfish Shippers List," published monthly and distributed to food control officials and other interested persons by FDA, Center for Food Safety and Applied Nutrition, Shellfish Sanitation Branch (HFF-344), 200 C Street, S.W., Washington, D.C. 20204.

4. Federal Food, Drug, and Cosmetic Act, 1938, as amended, U.S. Code, Title 21.

5. Public Health Service Act, as amended, U.S. Code, Title 42.

6. Fair Packaging and Labeling Act, Public Law 89-755, approved November 3, 1966.

7. American Public Health Association, Recommended Procedures for the Examination of Seawater and Shellfish, 4th Ed., 1970, APHA, Inc., 1015 15th Street, N.W., Washington, D.C. 20036.

8. Food and Drug Administration "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food," regulations, 21 CFR Part 110.

9. Food and Drug Administration, "Definitions and Standards for Food," "Fish and Shellfish" regulations, 21 CFR Part 161.

10. Food and Drug Administration, "Specific Administrative Decisions Regarding Interstate Shipments," "Shellfish," 21 CFR 1240.60.

11. Food and Drug Administration, "Food Service Sanitation on Land and Air Conveyances, and Vessels," "Special Food Requirements," 21 CFR 1250.26.

12. 1972 Shellfish Sanitation Agreement between Government of the United States of America and the Government of the Republic of Korea.

IV. PART

A. National Fisheries Administration
19th Floor Dae Wou Bldg.
5 Name Dae Mun Ro
Seoul, Korea

B. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
U.S.A.

V. LIAISON OFFICERS

A. Liaison Officer for NFA:

Fishery Attache
(currently Sang Chul Song)
Embassy of the Republic of Korea,
2320 Massachusetts Avenue
Washington, D.C. 20008
Telephone: (202) 939-5675 ext. 75

B. Liaison Officer for FDA:

Chief, Shellfish Sanitation Branch,
(currently David M. Dressel)
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
200 C Street, S.W.
Washington, D.C. 20204
Telephone: (202) 485-0149

VI. PERIOD OF AGREEMENT

This agreement will take effect when signed by representatives of both parties. It may be modified by mutual written consent or may be terminated by either party upon a 30-day advance written notice to the other party's liaison officer. Unless otherwise modified, this agreement will terminate 10 years after the effective date.

APPROVED AND ACCEPTED
FOR THE NATIONAL FISHERIES ADMINISTRATION,
MINISTRY OF AGRICULTURE, FORESTRY
AND FISHERIES
REPUBLIC OF KOREA

By:
Title: Administrator
Date: April 8, 1987

APPROVED AND ACCEPTED
FOR THE FOOD AND DRUG
ADMINISTRATION, DEPARTMENT
OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA

By: John M Taylor
Title: Associate Commissioner for Regulatory Affairs
Date: MAR 13 1987

FOOD AND DRUG ADMINISTRATION
COMPLIANCE POLICY GUIDES

GUIDE 7156x.10

CHAPTER 56x - MOUs - FOREIGN

SUBJECT: MOU with the United Kingdom regarding fresh and fresh frozen shellfish (225-80-2001) Modification #1)

MEMORANDUM OF UNDERSTANDING CONCERNING THE SANITARY CONTROL OF FRESH AND FROZEN MOLLUSCAN SHELLFISH DESTINED FOR EXPORTATION FROM ENGLAND TO THE UNITED STATES

Between The

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA

And The

DEPARTMENT OF SOCIAL SECURITY
UNITED KINGDOM

I. PURPOSE

The Food and Drug Administration (FDA) and the Department of Health and Social Security (DHSS) affirm by this memorandum their intention to cooperate in seeking to assure that fresh and fresh-frozen molluscan shellfish exported from England to the United States of America, are safe, wholesome, and have been harvested, processed, transported, and labeled in accordance with the provisions of the National Shellfish Sanitation Program (NSSP) and the requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. This document also defines terms and describes the responsibilities of FDA and DHSS in operation and management of the terms of this memorandum. By this document FDA officially recognizes DHSS as the certifying authority of shippers of fresh and frozen shellfish imports destined for United States markets.

II. BACKGROUND

This document is a modification of the original memorandum signed by both parties in September 1980, and supersedes that document.

III. SUBSTANCE OF AGREEMENT

A. TERMS

1. Advisory Agencies: Means the Fisheries Research Laboratory, Burnham-on-Crouch, and the laboratories of the Public Health Laboratory Service that provide analytical support to local shellfish control authorities associated with this memorandum.

2. Shellfish: Means all edible species of bivalved molluscus (i.e., oysters, clams, mussels, and cockles) except species of scallops.

3. Enforcement Agencies: Means Port Health Authorities and District, City, or Borough councils that have regulatory authority over the production, processing, and exportation of certified shellfish to the United States under the terms of this memorandum.

4. Lot: Means a collection of primary containers or units of the same size, type, and style, produced under conditions as nearly uniform as possible, designated by a common container code or marking, and in any event, no more than a day's production.

5. Central File: The single location where shellfish control program information, data, and reports are stored and maintained.

B. DHSS RESPONSIBILITIES

DHSS signs this memorandum on the basis that:

1. The respective enforcement agencies have agreed to use their best endeavors to ensure that shellfish exported to the United States originate from harvesting areas within waters that meet the terms of this memorandum.

2. The enforcement agencies have agreed to inspect the harvesting, relaying, transporting, and processing of fresh shellfish intended for export to the United States at sufficient frequency to confirm compliance with NSSP sanitary control practices. The enforcement agencies have agreed to make all records of their inspections available to advisory agencies to facilitate evaluations of those procedures.

3. The enforcement agencies have agreed to collate and

maintain files of laboratory results including routine data and data from quality assurance programs. Copies of appropriate enforcement agency data will be maintained in a central file by DHSS for review and evaluation by FDA as necessary.

4. Advisory agencies concerned with this program may participate in FDA quality assurance programs, including but not necessarily limited to pathogenic and indicator bacteria, heavy metals, radionuclides, shellfish toxins, and/or other toxic chemicals as may be necessary. They may also participate in the evaluation of methods, media and reagents, and equipment.

5. Enforcement agencies have agreed to use their best endeavors to ensure that exporters will export only shellfish that conform in all respects to the following conditions:

a. Harvesting, relaying, and/or depuration are in accordance with the applicable food and shellfish laws, regulations, and orders of the English central and local governemnt enforcement agencies having jurisdiction and of the NSSP guidelines.

b. All containers of all lots of shellfish exported to the United States are indentified by the shippers address, certification number, and lot number or code, together with all other information required by the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.

c. Any container of shellfish exported to the United States for use as bait is labled, "Not for Human Use", and the contents decharacterized by coloring with a permanent dye.

6. At the request of FDA, joint inspections may be made by FDA and DHSS officials of certified premises and growing and relaying areas used for the production of shellfish destined for export to the United States. Arrangements will be made to meet travel expenses of FDA officials making inspections in accordance with this memorandum while the officials are in England.

7. The DHSS will certify only those shellfish shipping firms that comply with NSSP recommended practices and notify FDA of the name, location, and certification number of those

firms on FD-3038B "Shellfish Certification".

If DHSS becomes aware that conditions required by the NSSP are not subsequently being met, the Department will cancel the certificate by sending a completed Form FD-3038C "Certification Cancellation" to FDA.

C. FDA RESPONSIBILITIES

FDA agrees to:

1. Publish names, locations, and certification numbers of shellfish shippers certified by DHSS upon receipt of Form FD-3038B. These firms will appear in the monthly publication of the Interstate Certified Shellfish Shippers List.

2. Provide limited training to technical personnel in laboratory procedures, growing area classification procedures, and shellfish sanitation program administration upon request of DHSS and subject to availability of funds for such purposes.

3. Inform DHSS of the reason or reasons for all FDA detentions of certified shellfish shipments from England. Additional information that will be provided will include but may not necessarily be limited to:

a. Commodity identification.
b. Commodity code, lot and certification number.
c. Name and address of the shipper.
d. Sampling procedure.
e. Methods of analysis and confirmation.
f. Administrative guidelines.

4. Make travel arrangements for, and pay round trip transportation expenses of its inspection team between the United States and England. FDA will also pay all per diem of the inspection team.

5. Participate with DHSS in a joint evaluation of the NSSP as it pertains to shellfish exports to England.

6. Advise DHSS of any questions from local food control officials concerning the safety or wholesomeness of shellfish imported into the United States from England.—FDA, if it receives such questions, will seek to determine the reason for the problem and inform the DHSS of any action taken under State and local laws or regulations with regard to such shellfish imports.

7. Recognize England as a participant in the NSSP with full rights

to participate in national workshops, cooperative research programs, seminars, training courses, and other NSSP activities and to make recommendations for changes or improvements in procedures, methods, standards and guidelines of the NSSP.

D. SHARED RESPONSIBILITIES

1. Both parties agree to an exchange of information concerning proposal changes in the following:

   a. Methods and procedures for sampling.
   b. Methods of analysis.
   c. Methods of confirmation.
   d. Administrative guidelines, tolerance, specification standards and nomenclature.

IV. LIAISON OFFICERS

For Department of Health and Social Security:

Environmental Health Officer (currently, Mr. Michael Jacob)
Department of Health and Social Security
Room A322, Alexander Fleming House
Elephant and Castle
London SE1, England
01-407-5522, Ext. 7315

For Food and Drug Administration:

Chief, Fisheries Technology Branch (currently, Mr. J. David Clem)
Bureau of Foods
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204
202-245-1557

V. PERIOD OF AGREEMENT

This document will become effective upon acceptance by both parties and will remain in effect indefinitely. It may be modified by mutual consent or terminated by either party upon a 30 day advance written notice to the other.

APPROVED AND ACCEPTED FOR
THE DEPARTMENT OF HEALTH AND
SOCIAL SECURITY, OF THE
UNITED KINGDOM

By:____________________

Title: Assistant Secretary

____

Date: 7 September 1982

APPROVED AND ACCEPTED FOR THE
FOOD AND DRUG ADMINISTRATION,
DEPARTMENT OF HEALTH AND
HUMAN SERVICES, UNITED STATES
OF AMERICA

By: Joseph P. Hile

Title: Associate Commissioner

for Regulatory Affairs

Date: JUL 29 1982

SUBJECT: MOU with Iceland concerning fresh and fresh frozen oysters, clams, and mussels (FDA-225-79-4008)

MEMORANDUM OF UNDERSTANDING

Between The

MINISTRY OF FISHERIES
GOVERNMENT OF ICELAND

And The

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
UNITED STATES OF AMERICA

The Ministry of Fisheries of Iceland and the Food and Drug Administration (FDA) of the Department of Health, Education, and Welfare of the United States of America affirm by this document their intention to cooperate in assuring that fresh and fresh frozen oysters, clams, and mussels exported to the United States are safe, wholesome, and have been harvested, transported, processed, and labeled in accordance with the provisions of the National Shellfish Sanitation Program (NSSP) and requirements of the Federal Food, Drug, and Cosmetic Act.

I. TERMS

For purposes of this Memorandum, both parties agree to the following definitions:

Lot—A collection of primary containers or units of the same size, type, and style, produced under conditions as nearly uniform as possible, designated by a common container code or marking, and in any event, no more than a day's production.

Central file—The single location where shellfish control program information, data, and reports are stored and maintained.

Coliform group—All of the aerobic and facultative anaerobic, gramnegative, nonsporeforming bacilli which ferment lactose with gas formation within 48 hours at 35° C.

Fecal coliform group--Any bacteria as defined under the coliform group which will produce gas in E. coli medium within 24 hours at 44.5° C (±0.2°) in a water bath.

Bait shellfish—Shucked shellfish labeled and intended for bait use only; not for human consumption.

Shellfish—All edible species of molluscan bivalves except scallop species from the family Pectinidae. Only molluscan bivalves that are offered for entry into the United States as fresh or fresh frozen products are intended for coverage under this Memorandum of Understanding.

Marine biotoxins—Natural toxins produced by marine dinoflagellates such as Gonyaulaz catenella, Gonyaulax tamarensis, and Gymnodinium breve and concentrated by shellfish during the feeding process.

II. FOOD AND DRUG ADMINISTRATION AND MINISTRY OF FISHERIES

A. Both parties agree to provide information concerning proposed changes in the following:

1. Methods and procedures for sampling.
2. Methods of analysis.
3. Methods of confirmation.
4. Administrative guidelines, tolerance, specification standards, and nomenclature.
5. Reference standards.
6. Inspectional procedures.

B. Both parties agree to inform each other on a timely basis of the following:

1. Proposed modification of existing Federal or local regulations.

2. Proposed new Federal regulations.

3. Proposed new legislation.

4. Proposed modifications to the National Shellfish Sanitation Program.

C. Both parties agree to name a liaison officer who will coordinate all matters relating to this Memorandum. The liaison officers will be responsible for facilitating exhanges of information and expeditiously informing other interested parties within their respective countries on shellfish control problems requiring prompt attention. Each party agrees to provide notification of any changes in liaison officer appointments. Such notification shall constitute an amendment to, and not require a revision of, this agreement.

The Iceland liaison officer is:

Thordur Asgeirsson
Deputy Secretary General

The FDA liaison officer is:

J. David Clem
Chief, Shellfish Sanitation Branch.

D. Both parties agree that the working language for documents exchanged under this Memorandum shall be in English.

III MINISTRY OF FISHERIES

A. The Ministry of Fisheries agrees to classify its shellfish harvesting water in accordance with the procedures and standards set forth in the National Shellfish Sanitation Program (NSSP). The Ministry of Fisheries will assure that only fresh and fresh frozen shellfish harvested from areas which meet NSSP approved water quality and marine biotoxin standards and processed according to NSSP guidelines will be exported to the United States.

B. The Ministry of Fisheries agrees to inspect harvesting, transporting, and processing operations of fresh and fresh frozen shellfish at sufficient frequency to assure compliance with the NSSP sanitary control practices.

C. The Ministry of Fisheries agrees to issue certifications only to those fresh and fresh frozen shellfish shipping firms that comply with NSSP recommended practices and to notify FDA of the name, location, and certification number of these firms on Form FD-3038b "Shellfish Certification". To cancel a firm's certification, the Ministry of Fisneries will send a completed Form FD-3038c "Certification Cancellation" to FDA.

D. The Ministry of Fisheries agrees to require all containers of all lots of fresh and fresh frozen shellfish exported to the United States of America to be identified by lot number and certification number, together with all other information required by the Federal Food, Drug, and Cosmetic Act.

E. The Ministry of Fisheries agrees to facilitate joint inspections by FDA and Ministry of Fisheries officials of Iceland's certified fresh and fresh frozen shellfish processing firms, approved growing waters, and related harvesting and handling practices. Such inspections will be made on an annual basis or at a frequency deemed appropriate to determine that the Ministry of Fisheries shellfish sanitation control program is equivalent to the NSSP recommended practices and that only safe and wholesome fresh and fresh frozen shellfish are being exported to the United States.

F The Ministry of Fisheries agrees to make travel arrangements for, and pay transportation expenses of, the FDA inspection team while the team is conducting inspections within Iceland.

G. The Ministry of Fisheries agrees to participate to the maximum extent possible in FDA's laboratory quality assurance programs. These may include:

1. Participation in the analysis of split samples of:

a. Seawater and shellfish meats for indicator bacteria or pathogens.

b. Shellfish meats for heavy metals or other chemical or radio-nuclide contaminants as may be necessary.

2. The evaluation of new methods and procedures, including reagents, media, or other materials and instruments and equipment performance.

H. The Ministry of Fisheries agrees to the establishment of a central office within Iceland to collate and maintain a central file of laboratory results, including routine monitoring data and data from quality assurance programs. Standard formats for collecting and reporting data will be used.

I. If lots of shucked shellfish are imported into the United States for use as bait, the Ministry of Fisheries will assure that each container is labeled "Not for human use" and the contents are decharacterized by use of a permanent colored dye.

J. Promulgation and enforcement of regulations governing the growing, harvesting, processing, and shipment of fresh or frozen shellfish produced by Iceland for export to the United States are the sole responsibility of the Ministry of Fisheries.

K. The Ministry of Fisheries cannot be held liable for damages resulting from defects or noncompliance of Icelandic fresh or fresh frozen shellfish products produced under the provisions of this MOU.

IV. FOOD AND DRUG ADMINISTRATION

A. FDA agrees to publish the names, locations, and certification numbers of certified firms submitted by the Ministry of Fisheries. The firms will appear in the Monthly INTERSTATE CERTIFIED SHELLFISH SHIPPERS LIST.

B. Upon request FDA will provide limited training to technical personnel in laboratory procedures, classification of shellfish growing areas, and inspection and administrative procedures.

C. Whenever Icelandic shellfish are detained by FDA due to noncompliance with NSSP agreed upon practices or applicable laws or regulations, FDA will inform the Ministry of Fisheries of the reason or reasons for the detention. This information will include:

1. Commodity lot and certification number.
2. Name and address of the shipper.
3. Reason for the detention.
4. Sampling procedure.
5. Methods of analysis and confirmation.
6. Administrative guidelines.

D. FDA agrees to make travel arrangements for, and pay round trip transportation expenses of, its inspection team between the United States and Iceland. FDA will also pay all per diem of the inspection team.

V. NATIONAL SHELLFISH SANITATION PROGRAM

Upon signing this agreement, the Ministry of Fisheries becomes an active participating member of the National Shellfish Sanitation program (NSSP). As a full member of the NSSP, the Ministry of Fisheries may participate in national workshops, cooperative research programs, seminars, training courses, and other activities designed for the timely exchange of technical information, assistance, and joint resolution of problems confronting the NSSP. The Ministry of Fisheries may also:

A. Participate in a joint evaluation of the United States program as it pertains to shellfish exports to Iceland.

B. Make recommendations for changes and improvements in NSSP guidelines, methods, and standards.

C. Be advised by FDA in the event a State or local food control official questions the certification, safety or wholesomeness of Iceland's imported shellfish. FDA will, if so informed, seek to determine the reason for the problem and inform the Ministry of Fisheries of any action taken relative to State and local laws or regulations governing such shellfish imports.

Both parties agree that this memorandum shall become effective on the date it is signed by both parties. It shall remain in effect, and govern all fresh and fresh frozen shellfish exported to the United States of America, pending revision or revocation at the request of either agency. Upon signature of both parties, this Memorandum of Understanding will be published in the FEDERAL REGISTER. A copy of the Memorandum will be available for public review at the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

In witness whereof, the agencies have executed this Memorandum.

s/ Jon L. Arnalds
Secretary General
Iceland Ministry of Fisheries

Date: October 25, 1978.

s/ Donald Kennedy
Commissioner
Food and Drug Administration
Department of Health
Education, and Welfare

Date: December 28, 1978.

Effective date. This Memorandum of Understanding became effective December 28, 1978.

REFERENCES 1/

1. U.S. Department of Health, Education, and Welfare, Public Health Service, National Shellfish Sanitation Program, Manual of Operations: Part I Sanitation of Shellfish Growing Areas, 1965 Revision; Part II Sanitation of the Harvesting and Processing of Shellfish, 1965 Revision; Part III Public Health Service Appraisal of State Shellfish Sanitation Program, 1965 Revision, PHS Publication No. 33.

2. "Official Methods of Analysis", 12th Ed., Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, D.C. 20044, 1975.

3. Food and Drug Administration, "Interstate Certified Shellfish Shippers List," published monthly and distributed to food control officials and other interested persons by FDA, Bureau of Foods, Shellfish Sanitation Branch (HFF-417), 200 C St. SW., Washington, D.C. 20204.

4. Federal Food, Drug, and Cosmetic Act, as amended, United States Code, Title 21.

5. Fair Packaging and Labeling Act, Pub. L. 89-755, approved November 3, 1966.

6. American Public Health Association, "Recommended Procedures for the Examination of Seawater and Shellfish," 4th Ed., 1970, APHA, Inc., 1015 18th St. NW., Washington, D.C. 20036.

7. Food and Drug Administration, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food" regulations, 21 CFR Part 110.

8. Food and Drug Administration, Definitions and Standards for Food, "Fish and Shellfish" regulations, 21 CFR Part 161.

1/ Filed as part of the original document

SUBJECT: Agreement with JAPAN on shellfish sanitation (FDA-225-75-2018)

SHELLFISH SANITATION AGREEMENT

Between

THE UNITED STATES OF AMERICA

And

JAPAN

Excellency:

I have the honor to refer to recent discussions between representatives of our two governments directed toward improving and standardizing shellfish sanitation practices and exchanging information on sanitary controls applied to the production and handling of fresh or frozen oysters, clams and mussels intended for shipment between Japan and the United States.

As a result of these discussions the following understandings were reached:

1. Uniform sanitation principles will be applied to the production and handling of all fresh or frozen oysters, clams and mussels intended for shipment between the two countries.

2. The principles in the Manual of Recommended Practice for Sanitary Control of the Shellfish Industry adopted by the United States Public Health Service, as amended from time to time, will be embodied in the relevant sanitary regulations in Japan.

3. The Ministry of Health and Welfare of Japan and the United States Public Health Service will exchange information on the state of compliance with these principles by the competent authorities in their respective countries and will maintain close contacts on matters concerning sanitary conditions of such shellfish.

4. Whenever sanitary observations of shellfish production areas or handling facilities are desired by either government, the other government will facilitate such observations.

5. Detailed arrangements for the implementation of this Agreement may be entered into from time to time by the United States Public Health Service and the Japanese Ministry of Health and Welfare.

6. This Agreement may be terminated by either Government giving thirty days written notice except that frozen oysters, clams and mussels packaged in accordance with the uniform sanitation principles under this Agreement will be accepted for a period of six months following the termination of the Agreement unless there are cogent public health reasons for prohibiting the importation of such products.

I have the honor to propose that if these understandings meet with the approval of the Government of the United States the present note and your Excellency's note in reply concerning therein shall constitute an agreement between our two governments, which agreement shall enter into force on the date of your Excellency's reply.

Accept, Excellency, the renewed assurances of my highest consideration.

/s/
Koichiro Asakai
Ambassador of Japan

Secretary of State
Department of State
Washington 25, D.C.

ARRANGEMENT BETWEEN THE UNITED STATES PUBLIC HEALTH SERVICE AND THE JAPANESE MINISTRY OF HEALTH AND WELFARE

In accordance with the provisions of paragraph 5 of the Agreement entered into on October 24, 1962 between the Government of the United States and the Government of Japan, the United States Public Health Service and the Ministry of Health and Welfare of Japan have entered into the arrangement as set forth below insofar as concerns fresh or frozen oysters, clams and mussels intended for shipment from Japan to the United States:

1. The principles of the Manual of Recommended Practice for Sanitary Control of the Shellfish Industry approved by the United States Public Health Service and the Canadian Department of National Health and Welfare, as amended from time to time, will apply to the sanitary regulation of shellfish production and certification of shellfish exporters in Japan. It is agreed that some modifications of the technical standards contained in this Manual may be needed to assure that the sanitary quality of oysters, clams and mussels produced in Japan for export to the United States will be as high as the sanitary quality of those produced in the United States. The Ministry of Health and Welfare will be consulted in advance by the United States Public Health Service in the case of any amendment to the Manual referred to in paragraph 2 of the Agreement.

2. The Japanese Ministry of Health and Welfare will notify the state of compliance as stipulated in paragraph 3 of the Agreement prior to May 30 of each year. These notifications will include lists of shippers holding operating permits in compliance with the principles of the Agreement.

3. If the state of compliance is acceptable to the United States Public Health Service, the names and permit numbers of the certified shippers will be included on the Public Health Service lists of certified shellfish shippers. The names and permit numbers of shippers so listed may be removed from the public lists by the Public Health Service (a) in the absence of evidence that the product has been produced and handled in accordance with these principles, (b) in a public health emergency, or (c) if there is evidence that the state of compliance with the agreed upon standards is less than that

required of the States of the United States by the Public Health Service in maintaining the sanitary quality of shellfish shipped in interstate commerce.

4. It is understood that fresh or frozen oysters, clams and mussels shipped from Japan to the United States under the terms of the Agreement will be subject to the provisions of the Federal Food, Drug and Cosmetic Act.

5. The shipment of fresh or frozen oysters, clams and mussels from the United States to Japan shall be the subject of corresponding subsequent arrangements.

Luther L. Terry, Surgeon General
for the United States Public Health Service

Yoshihiko Hasegawa, Counselor, Embassy of
Japan for the Ministry of Health and Welfare
of Japan

Date: October 24, 1962

✓ ✓ 225-81-2002

MEMORANDUM OF UNDERSTANDING
BETWEEN
NATIONAL MARINE FISHERIES SERVICE
AND THE
FOOD AND DRUG ADMINISTRATION

RELATIVE TO RESEARCH PROGRAMS FOR FISHERY PRODUCTS

I. Purpose:

The purpose of this Memorandum of Understanding is to improve and increase the cooperation/coordination of research efforts, avoid duplication, and make more efficient use of Federal resources supporting research programs for fishery products that are of joint interest to the National Marine Fisheries Service and the Food and Drug Administration. It sets forth the working arrangements which are to be followed or adopted to enable each agency to discharge, as effectively as possible, its responsibilities related to research activities for fishery products.

II. Background:

The Food and Drug Administration (FDA) of the Department of Health and Human Services is charged with the enforcement of the Federal Food, Drug and Cosmetic Act and Fair Packaging and Labeling Act. In fulfilling its responsibilities under these Acts, FDA directs its activities toward the protection of the public health and welfare of the Nation by ensuring that foods, including fish, are safe, wholesome and properly labeled. This is accomplished by: promulgating regulations dealing with the safety, quality and identity of seafood; establishing tolerances and guidelines for contaminants; inspecting the processing and distribution of foods; examining samples thereof to assure compliance with the Acts, and conducting research in the furtherance and improvement of the foregoing activities.

The National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce, under authorities established by the Agricultural Marketing Act, the Fish and Wildlife Act, the National Ocean Pollution Research and Development and Monitoring Act of 1978 and the Marine Protection, Research and Sanctuaries Act of 1972, is responsible for the development and maintenance of a comprehensive information base necessary to assure the safety, quality and identity of the supply of seafood to U.S. consumers. The two agencies have certain common or related objectives in conducting their respective research activities necessary to fulfill their responsibilities.

III. Substance of Agreement:

A. AREAS OF RESEARCH

The areas of research included in this Memorandum of Understanding cover those activities of mutual concern related to the safety, quality, nutrition and labeling requirements for fish and shellfish products.

B. MECHANISMS FOR COOPERATIVE/COORDINATED RESEARCH

Each agency will designate a central contact to whom communications dealing with this agreement or matters affected thereby, may first be referred to for attention. These persons will maintain continuing liaison with the other agency for the purpose of coordinating research programs of mutual concern, and shall establish a procedure for appropriate coordination of these programs. When either agency is unable to carry out any or all of its responsibilities under this Memorandum of Understanding, immediate notification should be provided to the other agency.

Both agencies will cooperate, where deemed appropriate, in planning and conducting research necessary to (1) assess the nature, level and significance of natural, environmental, and process-induced deleterious materials in fish and fishery products, (2) develop information concerning the quality and nutritional value of these products; and (3) provide the basis for their improved labeling. For these purposes, a research committee composed of four scientists from each agency will be established and will meet at six-month intervals to: determine extramural research needs of interest to both agencies; recommend joint research projects; recommend project assignments to the appropriate agency; recommend development of appropriate interagency agreements for transfer of funds for support of in-house or extramural research of interest to both agencies; develop joint analytical quality assurance programs; and review progress of in-house and extramural research of interest to both agencies. Chairperson responsibilities will rotate between the two agencies at yearly intervals.

Meetings, as necessary, will also be held by appropriate laboratory and staff personnel in the furtherance of these activities of mutual interest. Each agency will keep its customary records and make those related to the operation of this Memorandum of Understanding available to the other agency as mutually agreed upon.

C. SUPPLEMENTAL AGREEMENTS:

Nothing in this Memorandum of Understanding modifies other existing agreements or Memoranda of Understanding, nor does it preclude entering into separate agreements setting forth procedures for special programs which can be handled more efficiently and expeditiously by such other arrangements.

IV. Name and Address of Participating Agencies:

A. National Marine Fisheries Service
Page Building 2
3300 Whitehaven St. NW
Washington, DC 20235

B. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

V. Liaison Officers:

A. For the National Marine Fisheries Service:
Chief, Seafood Research, Inspection and Consumer
Services Division (Currently Mr. Thomas J. Billy)
Page Building 2
3300 Whitehaven St. NW
Washington, DC 20235
Telephone: (202) 634-7458

B. For the Food and Drug Administration:
Deputy Associate Director for Physical Sciences,
HFF-401 (Currently Charles F. Jelinek, Ph.D.)
Bureau of Foods
Food and Drug Administration
200 C St. SW
Washington, DC 20204
Telephone: (202) 245-1307

VVI. Period of Agreement:

This agreement, when accepted by both parties, will be effective from the date of the last signature and will continue indefinitely. It may be modified by mutual consent or may be terminated by either party upon a 30 day advance written notice to the other.

APPROVED AND ACCEPTED FOR THE
NATIONAL MARINE FISHERIES SERVICE

By ________
Terry L. Leitzell

Title Assistant Administrator

for Fisheries

Date MAY 8 1981

APPROVED AND ACCEPTED FOR THE
FOOD AND DRUG ADMINISTRATION

By ________
Joseph P. Hile

Title Associate Commissioner

for Regulatory Affairs

Date MAY 22 1981